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DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 25

[Docket No. FAA–2015–2393; Special Conditions No. 25–695–SC]

Special Conditions: Bombardier Inc. Model BD–700–2A12 and BD–700–2A13 Airplanes; Fuselage Post-Crash Fire Survivability

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final special conditions.

SUMMARY: These special conditions are issued for the Bombardier Inc. (Bombardier) Model BD–700–2A12 and BD–700–2A13 airplanes. These airplanes will have a novel or unusual design feature when compared to the state of technology envisioned in the airworthiness standards for transport category airplanes. This feature is an aluminum-lithium fuselage construction that may provide different levels of protection from post-crash fire threats than would similar airplanes constructed from traditional aluminum structure. The applicable airworthiness regulations do not contain adequate or appropriate safety standards for this design feature. These special conditions contain the additional safety standards that the Administrator considers necessary to establish a level of safety equivalent to that established by the existing airworthiness standards.

DATES: Effective September 5, 2017.

FOR FURTHER INFORMATION CONTACT: Alan Sinclair, FAA, Airframe and Cabin Safety Branch, ANM–115, Transport Airplane Directorate, Aircraft Certification Service, 1601 Lind Avenue SW., Renton, Washington, 98057–3356; telephone 425–227–2195; facsimile 425–227–1232.

SUPPLEMENTARY INFORMATION:

Background

On May 30, 2012, Bombardier applied for an amendment to type certificate no. T00003NY to include the new Model BD–700–2A12 and BD–700–2A13 airplanes. These airplanes are derivatives of the Model BD–700 series of airplanes and are marketed as the Bombardier Global 7000 (Model BD–700–2A12) and Global 8000 (Model BD–700–2A13). These airplanes are twin-engine, transport-category, executive-interior business jets. The maximum passenger capacity is 19 and the maximum takeoff weights are 106,250 lbs. (Model BD–700–2A12) and 104,800 lbs. (Model BD–700–2A13).

Type Certification Basis

Under the provisions of Title 14, Code of Federal Regulations (14 CFR) 21.101, Bombardier must show that the Model BD–700–2A12 and BD–700–2A13 airplanes meet the applicable provisions of the regulations listed in Type Certificate No. T00003NY, or the applicable regulations in effect on the date of application for the change, except for earlier amendments as agreed upon by the FAA.

If the Administrator finds that the applicable airworthiness regulations (*i.e.,* 14 CFR part 25) do not contain adequate or appropriate safety standards for the Model BD–700–2A12 and BD–700–2A13 airplanes because of a novel or unusual design feature, special conditions are prescribed under the provisions of § 21.16.

Special conditions are initially applicable to the model for which they are issued. Should the type certificate for that model be amended later to include any other model that incorporates the same novel or unusual design feature, or should any other model already included on the same type certificate be modified to incorporate the same novel or unusual design feature, these special conditions would also apply to the other model under § 21.101.

In addition to the applicable airworthiness regulations and special conditions, the Model BD–700–2A12 and BD–700–2A13 airplanes must comply with the fuel-vent and exhaust-emission requirements of 14 CFR part 34, and the noise-certification requirements of 14 CFR part 36.

The FAA issues special conditions, as defined in 14 CFR 11.19, in accordance with § 11.38, and they become part of the type-certification basis under § 21.101.

Novel or Unusual Design Feature

Bombardier Inc. Model BD–700–2A12 and BD–700–2A13 airplanes will incorporate the following novel or unusual design feature: The fuselage will be fabricated using aluminum-lithium alloy materials instead of conventional aluminum.

Discussion

The certification basis for the Bombardier Model BD–700–2A12 and BD–700–2A11 airplanes does not include the burn through requirements defined in § 25.856(b) because both airplane models have a passenger capacity of fewer than 20. The Model BD–700–2A12 and BD–700–2A13 airplanes are introducing a new material other than what has traditionally been shown to be survivable from a ''toxic'' standpoint. The applicant must ensure that the material being installed on an airplane does not introduce a new hazard that would reduce the survivability of the passengers during a post-crash situation, or that would provide levels of toxic fumes that would be lethal or incapacitating, thus preventing evacuation of the airplane in a crash scenario.

In accordance with § 21.16, fuselage structure that includes aluminum-lithium construction is an unusual design feature for large, transport-category airplanes certificated under 14 CFR part 25.

Regulations applicable to burn requirements, including §§ 25.853 and 25.856(a), remain valid for these airplanes, but do not protect against the threat generated from potentially toxic levels of gases produced from aluminum-lithium alloy materials.

These special conditions contain the additional safety standards that the Administrator considers necessary to establish a level of safety equivalent to that established by the existing airworthiness standards.

Discussion of Comments

Notice of Proposed Special Conditions No. 25–16–07–SC for the Bombardier Model BD–700–2A12 and BD–700–2A13 airplanes was published in the **Federal Register** on October 26, 2016 (81 FR 74347). One comment was received.

The commenter acknowledged that the use of the aluminum-lithium alloy would require full certification to the existing regulations. However, they contend that the material is not novel and unusual and does not require special conditions.

The FAA does not agree. While it is true that, with the level of lithium in the alloys presently tested, the proposed aluminum-lithium alloy does not appear to pose a significant risk, the existing regulations, as discussed above, do not adequately address the use of this specific alloy technology. Lithium metal is highly flammable and toxic; therefore, the FAA is concerned about the use of lithium in aircraft alloys. The FAA did not have data on the properties of aluminum-lithium when exposed to a post-crash fire threat prior to applying these special conditions.

Therefore, special conditions are required until the regulations are amended to provide sufficient requirements for the application of this new alloy technology.

Applicability

As discussed above, these special conditions are applicable to the Bombardier Model BD–700–2A12 and BD–700–2A13 airplanes. Should Bombardier apply at a later date for a change to the type certificate to include another model incorporating the same novel or unusual design feature, these special conditions would apply to the other model as well.

Conclusion

This action affects only one novel or unusual design feature on Bombardier Model BD–700–2A12 and BD–700–2A13 airplanes. It is not a rule of general applicabilit.

List of Subjects in 14 CFR Part 25

Aircraft, Aviation safety, Reporting and recordkeeping requirements.

The authority citation for these special conditions is as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701, 44702, 44704.

The Special Conditions

Accordingly, pursuant to the authority delegated to me by the Administrator, the following special conditions are issued as part of the type certification basis for Bombardier Model BD–700–2A12 and BD–700–2A13 airplanes.

The Model BD–700–2A12 and BD–700–2A13 airplanes must show that toxic levels of gases produced from the aluminum-lithium material, when exposed to a post-crash fire threat, are in no way an additional threat to the passengers, including, but not limited to, their ability to evacuate, when compared to traditional aluminum airplane materials.

Issued in Renton, Washington.

Victor Wicklund,

Manager, Transport Standards Branch, Aircraft Certification Service.

[FR Doc. 2017–16413 Filed 8–3–17; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 25

[Docket No. FAA–2017–0317; Special Conditions No. 25–694–SC]

Special Conditions: Embraer S.A. Model ERJ 190–300 Airplane; Flight Envelope Protection: Normal Load Factor (g) Limiting

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final special conditions; request for comments.

SUMMARY: These special conditions are issued for the Embraer S.A. (Embraer) Model ERJ 190–300 airplane. This airplane will have a novel or unusual design feature when compared to the state of technology envisioned in the airworthiness standards for transport-category airplanes. This design feature involves flight-envelope protection functions that limit such flight parameters as, for example, angle of attack, normal load factor, attitude, bank angle, and speed during normal operation. The applicable airworthiness regulations do not contain adequate or appropriate safety standards for this design feature. These special conditions contain the additional safety standards that the Administrator considers necessary to establish a level of safety equivalent to that established by the existing airworthiness standards.

DATES: This action is effective on Embraer S.A. on August 4, 2017. We must receive your comments by September 18, 2017.

ADDRESSES: Send comments identified by docket number FAA–2017–0317 using any of the following methods:

- *Federal eRegulations Portal:* Go to *http://www.regulations.gov/* and follow the online instructions for sending your comments electronically.
- *Mail:* Send comments to Docket Operations, M–30, U.S. Department of Transportation (DOT), 1200 New Jersey Avenue SE., Room W12–140, West Building Ground Floor, Washington, DC 20590–0001.
- *Hand Delivery or Courier:* Take comments to Docket Operations in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.
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Docket: Background documents or comments received may be read at *http://www.regulations.gov/* at any time. Follow the online instructions for accessing the docket or go to Docket Operations in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Joe Jacobsen, FAA, Airplane and Flight Crew Interface Branch, ANM–111, Transport Airplane Directorate, Aircraft Certification Service, 1601 Lind Avenue SW., Renton, Washington 98057–3356; telephone 425–227–2011; facsimile 425–227–1320.

SUPPLEMENTARY INFORMATION: The substance of these special conditions has been subject to the notice and comment period in several prior instances and has been derived without substantive change from those previously issued. It is unlikely that prior public comment would result in a significant change from the substance contained herein. Therefore, because a delay would significantly affect the certification of the airplane, the FAA has determined that prior public notice and comment are unnecessary and impracticable.

In addition, since the substance of these special conditions has been subject to the public comment process in several prior instances with no substantive comments received, the FAA finds it unnecessary to delay the effective date and finds that good cause exists for adopting these special conditions upon publication in the **Federal Register**.

The FAA is requesting comments to allow interested persons to submit views that may not have been submitted in response to the prior opportunities for comment described above.

Comments Invited

We invite interested people to take part in this rulemaking by sending written comments, data, or views. The most helpful comments reference a specific portion of the special conditions, explain the reason for any recommended change, and include supporting data.

We will consider all comments we receive by the closing date for comments. We may change these special conditions based on the comments we receive.

Background

On September 13, 2013, Embraer applied for an amendment to Type Certificate No. A57NM to include the new Model ERJ 190–300 airplane. The Model ERJ 190–300 airplane, which is a derivative of the Embraer Model ERJ 190–100 STD airplane currently approved under Type Certificate No. A57NM, is a 97- to 114-passenger transport-category airplane. The maximum take-off weight is 124,340 lbs (56,400 kg).

Type Certification Basis

Under the provisions of Title 14, Code of Federal Regulations (14 CFR) 21.101, Embraer must show that the Model ERJ 190–300 airplane meets the applicable provisions of the regulations listed in Type Certificate No. A57NM, or the applicable regulations in effect on the date of application for the change, except for earlier amendments as agreed upon by the FAA.

If the Administrator finds that the applicable airworthiness regulations (*i.e.,* 14 CFR part 25) do not contain adequate or appropriate safety standards for the Model ERJ 190–300 airplane because of a novel or unusual design feature, special conditions are prescribed under the provisions of § 21.16.

Special conditions are initially applicable to the model for which they are issued. Should the type certificate for that model be amended later to include any other model that incorporates the same novel or unusual design feature, or should any other model already included on the same type certificate be modified to incorporate the same novel or unusual design feature, these special conditions would also apply to the other model under § 21.101.

In addition to the applicable airworthiness regulations and special conditions, the Model ERJ 190–300 airplane must comply with the fuel-vent and exhaust-emission requirements of 14 CFR part 34 and the noise-certification requirements of 14 CFR part 36.

The FAA issues special conditions, as defined in 14 CFR 11.19, in accordance with § 11.38, and they become part of the type certification basis under § 21.101.

Novel or Unusual Design Features

The Embraer Model ERJ 190–300 airplane will incorporate the following novel or unusual design feature: Flight-envelope protection functions that limit such flight parameters as, for example, angle of attack, normal load factor, attitude, bank angle, and speed during normal operation.

The Model ERJ 190–300 airplane incorporates normal load-factor limiting on a full-time basis, which prevents the pilot from exceeding the positive or negative airplane limit load factor. The application of this load-factor limiting function affects airplane-handling characteristics and may compromise the airplane's maneuverability and controllability. The current regulations do not contain adequate safety standards for these novel protection features.

Discussion

The Embraer Model ERJ 190–300 design has a complex, fully digital flight-control system, referred to as fly-by-wire (FBW) architecture. This FBW architecture provides closed-loop flight-control laws and multiple protection functions.

Airplanes with conventional flight-control systems (mechanical linkages) are limited in the pitch axis only by the elevator surface area and deflection limit. The elevator-control power is normally derived for adequate controllability and maneuverability at the most critical longitudinal pitching moment. The result is that, for traditional airplanes, maneuverability in excess of limit structural design values, within a significant portion of the flight envelope, is possible.

Part 25 does not specify requirements or policy for demonstrating maneuver control that imposes any handling-qualities requirements beyond the design limit structural loads. Nevertheless, the availability of this excess maneuver capacity, in the event of extreme emergency such as upset recoveries or collision avoidance, is recognized.

These special conditions contain the additional safety standards that the Administrator considers necessary to establish a level of safety equivalent to that established by the existing airworthiness standards.

Applicability

As discussed above, these special conditions are applicable to the Embraer Model ERJ 190–300 airplane. Should Embraer apply at a later date for a change to the type certificate to include another model incorporating the same novel or unusual design feature, these special conditions would apply to that model as well.

Conclusion

This action affects only a certain novel or unusual design feature on one model of airplane. It is not a rule of general applicability.

List of Subjects in 14 CFR Part 25

Aircraft, Aviation safety, Reporting and recordkeeping requirements.

The authority citation for these special conditions is as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701, 44702, 44704.

The Special Conditions

Accordingly, pursuant to the authority delegated to me by the Administrator, the following special conditions are issued as part of the type certification basis for Embraer Model ERJ 190–300 airplanes.

1. Normal Load Factor (g) Limiting. To meet the intent of adequate maneuverability and controllability required by § 25.143(a); and in addition to the requirements of § 25.143(a), and in the absence of other limiting factors, the following special conditions apply, based on § 25.333(b):

a. The positive limiting load factor must not be less than:

i. 2.5 g for the normal state of the electronic flight-control system with the high-lift devices retracted up to V_{MO}/M_{MO}. The positive limiting load factor may gradually be reduced to 2.25 g above V_{MO}/M_{MO}.

ii. 2.0 g for the normal state of the electronic flight-control system with the high-lift devices extended.

b. The negative limiting load factor must be equal to or more negative than:

i. Minus 1.0 g for the normal state of the electronic flight-control system with the high-lift devices retracted.

ii. 0.0 g for the normal state of the electronic flight-control system with high-lift devices extended

c. Maximum reachable positive load factor, wings level, may be limited by the characteristics of the electronic

flight-control system or flight-envelope protections (other than load-factor protection), provided that:

i. The required values are readily achievable in turns, and

ii. Wings-level pitch-up is satisfactory.

d. Maximum achievable negative load factor may be limited by the characteristics of the electronic flight-control system or flight-envelope protections (other than load-factor protection), provided that:

i. Pitch-down responsiveness is satisfactory, and

ii. From level flight, 0g is readily achievable, or alternatively, a satisfactory trajectory change is readily achievable at operational speeds. For the FAA to consider a trajectory change as satisfactory, the applicant should propose and justify a pitch rate that provides sufficient maneuvering capability in the most critical scenarios.

e. Compliance demonstration with the above requirements may be performed without ice accretion on the airframe.

f. These special conditions do not impose an upper bound for the normal load-factor limit, nor do they require that the limiter exist. If the limit is set at a value beyond the structural design limit maneuvering load factor *n* of §§ 25.333(b), 25.337(b), and 25.337(c), then there should be a very obvious positive tactile feel built into the controller so that it serves as a deterrent to inadvertently exceeding the structural limit.

Issued in Renton, Washington.

Victor Wicklund,

Manager, Transport Standards Branch, Aircraft Certification Service.

[FR Doc. 2017–16414 Filed 8–3–17; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 25

[Docket No. FAA–2017–0356; Special Conditions No. 25–696–SC]

Special Conditions: Airbus Model A330–841 and A330–941 (A330 NEO) Airplanes; Interaction of Systems and Structures

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final special conditions; request for comments.

SUMMARY: These special conditions are issued for the Airbus Model A330 NEO airplanes. This airplane will have novel or unusual design features when compared to the state of technology envisioned in the airworthiness standards for transport-category airplanes. These design features include systems that, directly or as a result of failure or malfunction, affect airplane structural performance. The applicable airworthiness regulations do not contain adequate or appropriate safety standards for this design feature. These special conditions contain the additional safety standards that the Administrator considers necessary to establish a level of safety equivalent to that established by the existing airworthiness standards.

DATES: This action is effective on Airbus on August 4, 2017. We must receive your comments by September 18, 2017.

ADDRESSES: Send comments identified by docket number FAA–2017–0356 using any of the following methods:

- *Federal eRegulations Portal:* Go to *http://www.regulations.gov/* and follow the online instructions for sending your comments electronically.
- *Mail:* Send comments to Docket Operations, M–30, U.S. Department of Transportation (DOT), 1200 New Jersey Avenue SE., Room W12–140, West Building Ground Floor, Washington, DC 20590–0001.
- *Hand Delivery or Courier:* Take comments to Docket Operations in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.
- *Fax:* Fax comments to Docket Operations at 202–493–2251.

Privacy: The FAA will post all comments it receives, without change, to *http://www.regulations.gov/,* including any personal information the commenter provides. Using the search function of the docket Web site, anyone can find and read the electronic form of all comments received into any FAA docket, including the name of the individual sending the comment (or signing the comment for an association, business, labor union, etc.). DOT's complete Privacy Act Statement can be found in the **Federal Register** published on April 11, 2000 (65 FR 19477–19478).

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

FOR FURTHER INFORMATION CONTACT: Todd Martin, FAA, Airframe and Cabin Safety, ANM–115, Transport Airplane Directorate, Aircraft Certification Service, 1601 Lind Avenue SW., Renton, Washington 98057–3356; telephone 425–227–1178; facsimile 425–227–1320.

SUPPLEMENTARY INFORMATION:

The FAA has determined that notice of, and opportunity for prior public comment on, these special conditions is impracticable because these procedures would significantly delay issuance of the design approval and thus delivery of the affected airplanes.

In addition, the substance of these special conditions has been subject to the public comment process in several prior instances with no substantive comments received. The FAA therefore finds it unnecessary to delay the effective date and finds that good cause exists for making these special conditions effective upon publication in the **Federal Register**.

Comments Invited

We invite interested people to take part in this rulemaking by sending written comments, data, or views. The most helpful comments reference a specific portion of the special conditions, explain the reason for any recommended change, and include supporting data.

We will consider all comments we receive by the closing date for comments. We may change these special conditions based on the comments we receive.

Background

On January 20, 2015, Airbus applied for an amendment to Type Certificate no. A46NM to include the new Model A330–841 (A330–800NEO) and A330–941 (A330–900NEO) airplanes, collectively marketed as Model A330NEO airplanes. These airplanes, which are derivatives of the Model A330–200 and A330–300 airplanes currently approved under Type Certificate no. A46NM, are wide-body, jet-engine airplanes with a maximum takeoff weight of 533,519 pounds, and a passenger capacity of 257 (A330–841); or a maximum takeoff weight of 535,503 pounds, and a passenger capacity of 287 (A330–941).

Type Certification Basis

Under the provisions of Title 14, Code of Federal Regulations (14 CFR) 21.101, Airbus must show that the Model A330NEO airplanes meet the applicable provisions of the regulations listed in Type Certificate No. A46NM, or the applicable regulations in effect on the date of application for the change except for earlier amendments as agreed upon by the FAA.

If the Administrator finds that the applicable airworthiness regulations (*i.e.,* 14 CFR part 25) do not contain adequate or appropriate safety standards for Model A330NEO airplanes because of a novel or unusual design feature, special conditions are prescribed under the provisions of § 21.16.

Special conditions are initially applicable to the model for which they are issued. Should the type certificate for that model be amended later to include any other model that incorporates the same novel or unusual design feature, or should any other model already included on the same type certificate be modified to incorporate the same novel or unusual design feature, these special conditions would also apply to the other model under § 21.101.

In addition to the applicable airworthiness regulations and special conditions, the Airbus Model A330NEO airplanes must comply with the fuel-vent and exhaust-emission requirements of 14 CFR part 34 and the noise-certification requirements of 14 CFR part 36.

The FAA issues special conditions, as defined in 14 CFR 11.19, in accordance with § 11.38, and they become part of the type certification basis under § 21.101.

Novel or Unusual Design Features

The Airbus Model A330NEO airplanes will incorporate the following novel or unusual design features:

Systems that, directly or as a result of failure or malfunction, affect airplane structural performance. That is, the airplane's systems affect how it responds in maneuver and gust conditions, and thereby affect its structural capability. These systems may also affect the aeroelastic stability of the airplane. Such systems include flight control systems, autopilots, stability augmentation systems, load alleviation systems, and fuel management systems. These systems represent novel and unusual features when compared to the technology envisioned in the current airworthiness standards.

Discussion

Special conditions have been applied on past airplane programs to require consideration of the effects of systems on structures. The regulatory authorities and industry developed standardized criteria in the Aviation Rulemaking Advisory Committee (ARAC) forum based on the criteria defined in Advisory Circular (AC) 25.672–1, dated November 15, 1983. The ARAC recommendations have been incorporated in European Aviation Safety Agency (EASA) Certification Specifications (CS) 25.302 and CS 25 Appendix K, which are applicable to Airbus. FAA rulemaking on this subject is not complete, thus the need for the special conditions.

The special conditions are similar to those previously applied to other airplane models and to the requirements of CS 25.302. The major differences between these special conditions and the current CS 25.302 are as follows:

(1) Both the special conditions and CS 25.302 (and by reference Appendix K) specify the design load conditions to be considered. Effects of Systems on Structure, special conditions 2.a. and 3.b.i., clarify that, in some cases, different load conditions are to be considered due to other special conditions or equivalent-level-of-safety findings.

(2) Both the special conditions (see special condition 5, below) and CS 25.302 allow consideration of the probability of being in a dispatched configuration when assessing subsequent failures and potential ''continuation of flight'' loads. The special conditions, however, also allow using probability when assessing failures that induce loads at the ''time of occurrence,'' whereas CS 25.302 does not.

These special conditions contain the additional safety standards that the Administrator considers necessary to establish a level of safety equivalent to that established by the existing airworthiness standards.

Applicability

As discussed above, these special conditions are applicable to Airbus Model A330NEO airplanes. Should Airbus apply at a later date for a change to the type certificate to include another model incorporating the same novel or unusual design feature, these special conditions would apply to that model as well.

Conclusion

This action affects only certain novel or unusual design features on one model series of airplanes. It is not a rule of general applicability.

The substance of these special conditions has been subject to the notice and comment period in several prior instances and has been derived without substantive change from those previously issued. It is unlikely that prior public comment would result in a significant change from the substance contained herein. Therefore, because a delay would significantly affect the certification of the airplane, which is imminent, the FAA has determined that prior public notice and comment are unnecessary and impracticable, and good cause exists for adopting these special conditions upon publication in the **Federal Register**. The FAA is requesting comments to allow interested persons to submit views that may not have been submitted in response to the prior opportunities for comment described above.

List of Subjects in 14 CFR Part 25

Aircraft, Aviation safety, Reporting and recordkeeping requirements.

The authority citation for these special conditions is as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701, 44702, 44704.

The Special Conditions

Accordingly, pursuant to the authority delegated to me by the Administrator, the following special conditions are issued as part of the type certification basis for Airbus Model A330–841 and A330–941 airplanes.

For airplanes equipped with systems that affect structural performance, either directly or as a result of a failure or malfunction, the influence of these systems and their failure conditions must be taken into account when showing compliance with the requirements of part 25, subparts C and D.

For airplanes equipped with flight-control systems, autopilots, stability-augmentation systems, load-alleviation systems, fuel-management systems, and other systems that either directly, or as a result of failure or malfunction, affect structural performance, the following criteria must be used for showing compliance. If these special conditions are used for other systems, it may be necessary to adapt the criteria to the specific system.

1. The criteria defined herein only address the direct structural consequences of the system responses and performance. They cannot be considered in isolation, but should be included in the overall safety evaluation of the airplane. These criteria may, in some instances, duplicate standards already established for this evaluation. These criteria are only applicable to structure the failure of which could prevent continued safe flight and landing. Specific criteria that define acceptable limits on handling characteristics or stability requirements, when operating in the system-degraded or inoperative mode, are not provided in these special conditions.

2. Depending upon the specific characteristics of the airplane, additional studies that go beyond the

criteria provided in these special conditions may be required to demonstrate the airplane's capability to meet other realistic conditions, such as alternative gust or maneuver descriptions for an airplane equipped with a load-alleviation system.

3. The following definitions are applicable to these special conditions.

a. *Structural performance:* Capability of the airplane to meet the structural requirements of part 25.

b. *Flight limitations:* Limitations that can be applied to the airplane flight conditions following an in-flight occurrence, and that are included in the airplane flight manual (*e.g.,* speed limitations, avoidance of severe weather conditions, etc.).

c. *Operational limitations:* Limitations, including flight limitations, that can be applied to the airplane operating conditions before dispatch (*e.g.,* fuel, payload and Master Minimum Equipment List limitations).

d. *Probabilistic terms:* Terms such as probable, improbable, and extremely improbable, as used in these special conditions, are the same as those used in § 25.1309.

e. *Failure condition:* This term is the same as that used in § 25.1309. However, these special conditions apply only to system-failure conditions that affect the structural performance of the airplane (*e.g.,* system-failure conditions that induce loads, change the response of the airplane to inputs such as gusts or pilot actions, or lower flutter margins).

Effects of Systems on Structures

1. *General.* The following criteria will be used in determining the influence of a system and its failure conditions on the airplane structure.

2. *System fully operative.* With the system fully operative, the following apply:

a. Limit loads must be derived in all normal operating configurations of the system from all the limit conditions specified in part 25, subpart C (or defined by special conditions or findings of equivalent level of safety in lieu of those specified in subpart C), taking into account any special behavior of such a system or associated functions, or any effect on the structural performance of the airplane that may occur up to the limit loads. In particular, any significant nonlinearity (rate of displacement of control surface, thresholds, or any other system nonlinearities) must be accounted for in a realistic or conservative way when deriving limit loads from limit conditions.

b. The airplane must meet the strength requirements of part 25 (static strength, residual strength), using the specified factors to derive ultimate loads from the limit loads defined above. The effect of nonlinearities must be investigated beyond limit conditions to ensure that the behavior of the system presents no anomaly compared to the behavior below limit conditions. However, conditions beyond limit conditions need not be considered when it can be shown that the airplane has design features that will not allow it to exceed those limit conditions.

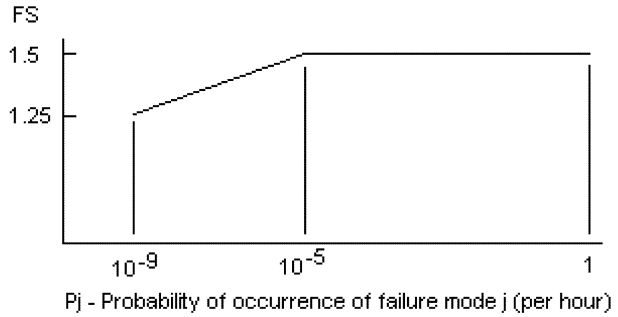
c. The airplane must meet the aeroelastic stability requirements of § 25.629.

3. *System in the failure condition.* For any system-failure condition not shown to be extremely improbable, the following apply:

a. At the time of occurrence. Starting from 1g level flight conditions, a realistic scenario, including pilot corrective actions, must be established to determine the loads occurring at the time of failure and immediately after the failure.

i. For static-strength substantiation, these loads, multiplied by an appropriate factor of safety that is related to the probability of occurrence of the failure, are ultimate loads to be considered for design. The factor of safety is defined in Figure 1, below.

Figure 1: Factor of safety (FS) at the time of occurrence



ii. For residual-strength substantiation, the airplane must be able to withstand two thirds of the ultimate loads defined in special condition 3.a.i. For pressurized cabins, these loads must be combined with the normal operating differential pressure.

iii. Freedom from aeroelastic instability must be shown up to the speeds defined in § 25.629(b)(2). For failure conditions that result in speeds beyond V_C/M_C, freedom from aeroelastic instability must be shown to increased speeds, so that the margins intended by § 25.629(b)(2) are maintained.

iv. Failures of the system that result in forced structural vibrations (oscillatory failures) must not produce loads that could result in detrimental deformation of primary structure.

b. For the continuation of the flight. For the airplane in the system-failed state, and considering any appropriate reconfiguration and flight limitations, the following apply:

i. The loads derived from the following conditions (or defined by special conditions or findings of equivalent level of safety in lieu of the following conditions) at speeds up to V_C/M_C (or the speed limitation prescribed for the remainder of the flight) must be determined:

1. The limit symmetrical maneuvering conditions specified in §§ 25.331 and 25.345.

2. the limit gust and turbulence conditions specified in §§ 25.341 and 25.345.

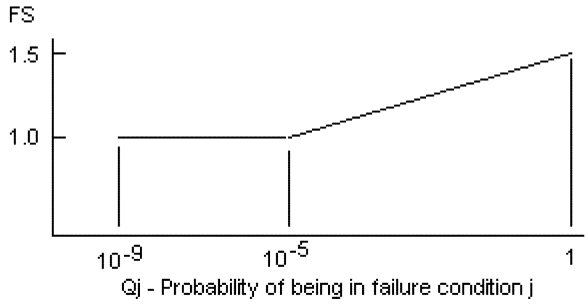
3. the limit rolling conditions specified in § 25.349, and the limit unsymmetrical conditions specified in §§ 25.367, and 25.427(b) and (c).

4. the limit yaw-maneuvering conditions specified in § 25.351.

5. the limit ground-loading conditions specified in §§ 25.473, 25.491, 25.493(d), and 25.503.

ii. For static-strength substantiation, each part of the structure must be able to withstand the loads in special condition 3.b.i., multiplied by a factor of safety depending on the probability of being in this failure state. The factor of safety is defined in Figure 2, below.

Figure 2: Factor of safety (FS) for continuation of flight



$Q_j = (T_j)(P_j)$

Where:

T_j = Average time spent in failure mode j (in hours)

P_j = Probability of occurrence of failure mode j (per hour)

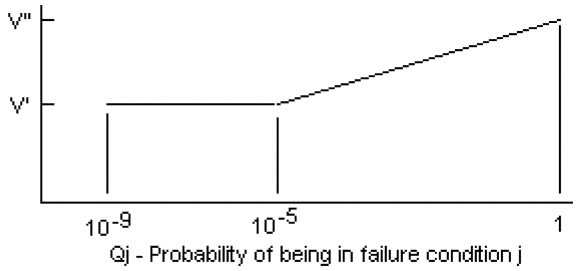
Note: If P_j is greater than 10^{-3} per flight hour, then a 1.5 factor of safety must be applied to all limit load conditions specified in part 25, subpart C.

iii. For residual-strength substantiation, the airplane must be able to withstand two-thirds of the ultimate loads defined in paragraph 3.b.ii. of these special conditions. For pressurized cabins, these loads must be combined with the normal operating differential pressure.

iv. If the loads induced by the failure condition have a significant effect on fatigue or damage tolerance, then their effects must be taken into account.

v. Freedom from aeroelastic instability must be shown up to a speed determined from Figure 3, below. Flutter clearance speeds V′ and V″ may be based on the speed limitation specified for the remainder of the flight using the margins defined by § 25.629(b).

Figure 3: Clearance speed



V′ = Clearance speed as defined by § 25.629(b)(2).

V″ = Clearance speed as defined by § 25.629(b)(1).

$Q_j = (T_j)(P_j)$

Where:

T_j = Average time spent in failure mode j (in hours)

P_j = Probability of occurrence of failure mode j (per hour)

Note: If P_j is greater than 10^{-3} per flight hour, then the flutter clearance speed must not be less than V″.

vi. Freedom from aeroelastic instability must also be shown up to V′ in Figure 3, above, for any probable system-failure condition, combined with any damage required or selected for investigation by § 25.571(b).

c. Consideration of certain failure conditions may be required by other sections of part 25 regardless of calculated system reliability. Where analysis shows the probability of these failure conditions to be less than 10^{-9} per flight hour, criteria other than those specified in this paragraph may be used for structural substantiation to show continued safe flight and landing.

4. *Failure indications.* For system-failure detection and indication, the following apply:

a. The system must be checked for failure conditions, not extremely improbable, that degrade the structural capability below the level required by part 25, or that significantly reduce the reliability of the remaining system. As far as reasonably practicable, the flightcrew must be made aware of these failures before flight. Certain elements of the control system, such as mechanical and hydraulic components, may use special periodic inspections, and electronic components may use daily checks, in lieu of detection and indication systems, to achieve the objective of this requirement. These certification-maintenance requirements

must be limited to components that are not readily detectable by normal detection-and-indication systems, and where service history shows that inspections will provide an adequate level of safety.

b. The existence of any failure condition, not extremely improbable, during flight, that could significantly affect the structural capability of the airplane, and for which the associated reduction in airworthiness can be minimized by suitable flight limitations, must be signaled to the flightcrew. For example, failure conditions that result in a factor of safety between the airplane strength and the loads of part 25, subpart C below 1.25, or flutter margins below V″, must be signaled to the crew during flight.

5. *Dispatch with known failure conditions.* If the airplane is to be dispatched in a known system-failure condition that affects structural performance, or that affects the reliability of the remaining system to maintain structural performance, then the provisions of these special conditions must be met, including the provisions of special condition 2 for the dispatched condition, and special condition 3 for subsequent failures. Expected operational limitations may be taken into account in establishing P_j as the probability of failure occurrence for determining the safety margin in Figure 1. Flight limitations and expected operational limitations may be taken into account in establishing Q_j as the combined probability of being in the dispatched failure condition and the subsequent failure condition for the safety margins in Figures 2 and 3. These limitations must be such that the probability of being in this combined failure state, and then subsequently encountering limit load conditions, is extremely improbable. No reduction in these safety margins is allowed if the subsequent system-failure rate is greater than 10^{-3} per flight hour.

Issued in Renton, Washington.

Victor Wicklund,

Manager, Transport Standards Branch, Aircraft Certification Service.

[FR Doc. 2017–16416 Filed 8–3–17; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 25

[Docket No. FAA–2017–0732; Special Conditions No. 25–697–SC]

Special Conditions: Embraer S.A., Model ERJ 190–300 Series Airplanes; Design Roll Maneuver for Electronic Flight Controls

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final special conditions; request for comments.

SUMMARY: These special conditions are issued for the Embraer S.A. (Embraer) Model ERJ 190–300 series airplanes. These airplanes will have a novel or unusual design feature when compared to the state of technology envisioned in the airworthiness standards for transport category airplanes. This design feature is an electronic flight control system (EFCS) that provides control of the airplane through pilot inputs to the flight computer. The applicable airworthiness regulations do not contain adequate or appropriate safety standards for this design feature. These special conditions contain the additional safety standards that the Administrator considers necessary to establish a level of safety equivalent to that established by the existing airworthiness standards.

DATES: This action is effective on Embraer on August 4, 2017. We must receive your comments by September 18, 2017.

ADDRESSES: Send comments identified by docket number FAA–2017–0732 using any of the following methods:

- *Federal eRegulations Portal:* Go to *http://www.regulations.gov/*and follow the online instructions for sending your comments electronically.
- *Mail:* Send comments to Docket Operations, M–30, U.S. Department of Transportation (DOT), 1200 New Jersey Avenue SE., Room W12–140, West Building Ground Floor, Washington, DC 20590–0001.
- *Hand Delivery or Courier:* Take comments to Docket Operations in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.
- *Fax:* Fax comments to Docket Operations at 202–493–2251.

Privacy: The FAA will post all comments it receives, without change, to *http://www.regulations.gov/,* including any personal information the commenter provides. Using the search function of the docket Web site, anyone can find and read the electronic form of all comments received into any FAA docket, including the name of the individual sending the comment (or signing the comment for an association, business, labor union, etc.). DOT's complete Privacy Act Statement can be found in the **Federal Register** published on April 11, 2000 (65 FR 19477–19478).

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

FOR FURTHER INFORMATION CONTACT: Greg Schneider, FAA, Airframe and Cabin Safety Branch, ANM–115, Transport Airplane Directorate, Aircraft Certification Service, 1601 Lind Avenue SW., Renton, Washington, 98057–3356; telephone 425–227–2116; facsimile 425–227–1320.

SUPPLEMENTARY INFORMATION: The FAA has determined that notice of, and opportunity for prior public comment on, these special conditions is impracticable because these procedures would delay issuance of the design approval and thus delivery of the affected airplane.

In addition, the substance of these special conditions has been subject to the public comment process in several prior instances with no substantive comments received. The FAA finds it is unnecessary to delay the effective date and finds that good cause exists for adopting these special conditions upon publication in the **Federal Register**.

Comments Invited

The FAA is requesting comments to allow interested persons to submit views that may not have been submitted in response to the prior opportunities for comment described above. We invite interested people to take part in this rulemaking by sending written comments, data, or views. The most helpful comments reference a specific portion of the special conditions, explain the reason for any recommended change, and include supporting data.

We will consider all comments we receive by the closing date for comments. We may change these special conditions based on the comments we receive.

Background

On September 13, 2013, Embraer applied for an amendment to Type

Certificate (TC) no. A57NM to include the new Model ERJ 190–300 airplanes. The Model ERJ 190–300 airplane, which is a derivative of the Model ERJ 190–100 STD airplane currently approved under TC no. A57NM, is a 97–114 passenger transport-category airplane with two Pratt & Whitney Model PW1900G engines, a new wing design with a high aspect ratio and raked wingtip, and a digital fly-by-wire electronic flight-control system.

The flight-control system for the Model ERJ 190–300 airplane does not have a direct mechanical link nor a linear gain between the airplane flight-control surface and the pilot's flight-deck control device, which is not accounted for in title 14, Code of Federal Regulations (14 CFR) 25.349(a). Instead, a flight-control computer commands the airplane flight-control surfaces, based on input received from the flight-deck control device. The flight-control computer modifies pilot input before the command is given to the flight-control surface.

Type Certification Basis

Under the provisions of 14 CFR 21.101, Embraer must show that the Model ERJ 190–300 airplane meets the applicable provisions of the regulations listed in Type Certificate No. A57NM or the applicable regulations in effect on the date of application for the change, except for earlier amendments as agreed upon by the FAA.

If the Administrator finds that the applicable airworthiness regulations (*i.e.,* 14 CFR part 25) do not contain adequate or appropriate safety standards for the Model ERJ 190–300 airplane because of a novel or unusual design feature, special conditions are prescribed under the provisions of § 21.16.

Special conditions are initially applicable to the Model for which they are issued. Should the type certificate for that model be amended later to include any other model that incorporates the same novel or unusual design features, or should any other model already included on the same type certificate be modified to incorporate the same novel or unusual design feature, these special conditions would also apply to the other model under § 21.101.

In addition to the applicable airworthiness regulations and special conditions, the ERJ 190–300 must comply with the fuel vent and exhaust emission requirements of 14 CFR part 34 and the noise-certification requirements of 14 CFR part 36.

The FAA issues special conditions, as defined in 14 CFR 11.19, in accordance with § 11.38, and they become part of the type certification basis under § 21.101.

Novel or Unusual Design Features

The ERJ 190–300 will incorporate the following novel or unusual design features: An electronic flight control system that provides control of the airplane through pilot inputs to the flight computer. Current part 25 airworthiness regulations account for control laws where aileron deflection is proportional to control stick deflection. They do not address any nonlinearities, *i.e.,* situations where output does not change in the same proportion as input, or other effects on aileron actuation that may be caused by electronic flight controls.

Discussion

These special conditions differ from current regulatory requirements in that they require that the roll maneuver result from defined movements of the cockpit roll control as opposed to defined aileron deflections. Also, these special conditions require an additional load condition at design maneuvering speed (V_A), in which the cockpit roll control is returned to neutral following the initial roll input.

These special conditions differ from similar special conditions previously issued on this topic. These special conditions are limited to the roll axis only, whereas other special conditions also included pitch and yaw axes. Special conditions are no longer needed for the yaw axis because 14 CFR 25.351 was revised at Amendment 25–91 to take into account effects of an electronic flight control system. No special conditions are needed for the pitch axis because the method that Embraer proposed for the pitch maneuver takes into account effects of an electronic flight control system.

These special conditions contain the additional safety standards that the Administrator considers necessary to establish a level of safety equivalent to that established by the existing airworthiness standards.

Applicability

As discussed above, these special conditions are applicable to the Model ERJ 190–300 airplanes. Should Embraer apply at a later date for a change to the type certificate to include another model incorporating the same novel or unusual design feature, these special conditions would apply to that model as well.

Conclusion

This action affects only certain novel or unusual design features on one model of airplanes. It is not a rule of general applicability.

List of Subjects in 14 CFR Part 25

Aircraft, Aviation safety, Reporting and recordkeeping requirements.

The authority citation for these special conditions is as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701, 44702, 44704.

The Special Conditions

Accordingly, pursuant to the authority delegated to me by the Administrator, the following special conditions are issued as part of the type certification basis for the Embraer Model ERJ 190–300 series airplanes.

In lieu of compliance to 14 CFR 25.349(a), the Embraer Model ERJ 190–300 airplane must comply with the following:

The following conditions, speeds, and cockpit roll control motions (except as the motions may be limited by pilot effort) must be considered in combination with an airplane load factor of zero and of two-thirds of the positive maneuvering factor used in design. In determining the resulting control surface deflections, the torsional flexibility of the wing must be considered in accordance with 14 CFR 25.301(b).

(a) Conditions corresponding to steady rolling velocities must be investigated. In addition, conditions corresponding to maximum angular acceleration must be investigated for airplanes with engines or other weight concentrations outboard of the fuselage. For the angular acceleration conditions, zero rolling velocity may be assumed in the absence of a rational time history investigation of the maneuver.

(b) At V_A, sudden movement of the cockpit roll control up to the limit is assumed. The position of the cockpit roll control must be maintained until a steady roll rate is achieved and then must be returned suddenly to the neutral position.

(c) At V_C, the cockpit roll control must be moved suddenly and maintained so as to achieve a roll rate not less than that obtained in paragraph (b).

(d) At V_D, the cockpit roll control must be moved suddenly and maintained so as to achieve a roll rate not less than one third of that obtained in paragraph (b).

Issued in Renton, Washington.

Victor Wicklund,

Manager, Transport Standards Branch, Aircraft Certification Service.

[FR Doc. 2017–16417 Filed 8–3–17; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 25

[Docket No. FAA–2017–0318; Special Conditions No. 25–693–SC]

Special Conditions: Embraer S.A. Model ERJ 190–300 Airplane; Interaction of Systems and Structures

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final special conditions; request for comments.

SUMMARY: These special conditions are issued for the Embraer S.A. (Embraer) Model ERJ 190–300 airplane. This airplane will have novel or unusual design features when compared to the state of technology envisioned in the airworthiness standards for transport-category airplanes. These design features include systems that, directly or as a result of failure or malfunction, affect airplane structural performance. The applicable airworthiness regulations do not contain adequate or appropriate safety standards for this design feature. These special conditions contain the additional safety standards that the Administrator considers necessary to establish a level of safety equivalent to that established by the existing airworthiness standards.

DATES: This action is effective on Embraer on August 4, 2017. Send your comments by September 18, 2017.

ADDRESSES: Send comments identified by docket number FAA–2017–0318 using any of the following methods:

- *Federal eRegulations Portal:* Go to *http://www.regulations.gov/* and follow the online instructions for sending your comments electronically.
- *Mail:* Send comments to Docket Operations, M–30, U.S. Department of Transportation (DOT), 1200 New Jersey Avenue SE., Room W12–140, West Building Ground Floor, Washington, DC 20590–0001.
- *Hand Delivery or Courier:* Take comments to Docket Operations in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.
- *Fax:* Fax comments to Docket Operations at 202–493–2251.

Privacy: The FAA will post all comments it receives, without change, to *http://www.regulations.gov/,* including any personal information the commenter provides. Using the search function of the docket Web site, anyone can find and read the electronic form of all comments received into any FAA docket, including the name of the individual sending the comment (or signing the comment for an association, business, labor union, etc.). DOT's complete Privacy Act Statement can be found in the **Federal Register** published on April 11, 2000 (65 FR 19477–19478).

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

FOR FURTHER INFORMATION CONTACT: Greg Schneider, FAA, Airframe and Cabin Safety Branch, ANM–115, Transport Airplane Directorate, Aircraft Certification Service, 1601 Lind Avenue SW., Renton, Washington 98057–3356; telephone 425–227–2116; facsimile 425–227–1320.

SUPPLEMENTARY INFORMATION: The FAA has determined that notice of, and opportunity for prior public comment on, these special conditions is impracticable because these procedures would significantly delay issuance of the design approval and thus delivery of the affected airplanes.

In addition, the substance of these special conditions has been subject to the public-comment process in several prior instances with no substantive comments received. The FAA therefore finds it unnecessary to delay the effective date and that good cause exists for making these special conditions effective upon publication in the **Federal Register**.

Comments Invited

We invite interested people to take part in this rulemaking by sending written comments, data, or views. The most helpful comments reference a specific portion of the special conditions, explain the reason for any recommended change, and include supporting data.

We will consider all comments we receive by the closing date for comments. We may change these special conditions based on the comments we receive.

Background

On September 13, 2013, Embraer applied for an amendment to Type Certificate No. A57NM to include the new Model ERJ 190–300 airplane. The Model ERJ 190–300 airplane, which is a derivative of the Embraer Model ERJ 190–100 STD airplane currently approved under Type Certificate No. A57NM, is a 97- to 114-passenger transport-category airplane. The maximum take-off weight is 124,340 lbs (56,400 kg).

Type Certification Basis

Under the provisions of Title 14, Code of Federal Regulations (14 CFR) 21.101, Embraer must show that the Model ERJ 190–300 airplane meets the applicable provisions of the regulations listed in Type Certificate No. A57NM, or the applicable regulations in effect on the date of application for the change, except for earlier amendments as agreed upon by the FAA.

If the Administrator finds that the applicable airworthiness regulations (*i.e.,* 14 CFR part 25) do not contain adequate or appropriate safety standards for the Model ERJ 190–300 airplane because of a novel or unusual design feature, special conditions are prescribed under the provisions of § 21.16.

Special conditions are initially applicable to the model for which they are issued. Should the type certificate for that model be amended later to include any other model that incorporates the same novel or unusual design feature, or should any other model already included on the same type certificate be modified to incorporate the same novel or unusual design feature, these special conditions would also apply to the other model under § 21.101.

In addition to the applicable airworthiness regulations and special conditions, the Model ERJ 190–300 airplane must comply with the fuel-vent and exhaust-emission requirements of 14 CFR part 34 and the noise-certification requirements of 14 CFR part 36.

The FAA issues special conditions, as defined in 14 CFR 11.19, in accordance with § 11.38, and they become part of the type certification basis under § 21.101.

Novel or Unusual Design Features

The Embraer Model ERJ 190–300 airplane will incorporate the following novel or unusual design feature:

Systems that, directly or as a result of failure or malfunction, affect airplane structural performance. That is, the

airplane's systems affect how it responds in maneuver and gust conditions, and thereby affect its structural capability. These systems may also affect the aeroelastic stability of the airplane. Such systems include flight control systems, autopilots, stability augmentation systems, load alleviation systems, and fuel management systems. These systems represent novel and unusual features when compared to the technology envisioned in the current airworthiness standards.

Discussion

Special conditions have been applied on past airplane programs to require consideration of the effects of systems on structures. The regulatory authorities and industry developed standardized criteria in the Aviation Rulemaking Advisory Committee (ARAC) forum based on the criteria defined in Advisory Circular (AC) 25.672–1, dated November 15, 1983. The ARAC recommendations have been incorporated in European Aviation Safety Agency (EASA) Certification Specifications (CS) 25.302 and CS 25 Appendix K, which are applicable to Embraer. FAA rulemaking on this subject is not complete, thus the need for the special conditions.

The special conditions are similar to those previously applied to other airplane models and to the requirements of CS 25.302. The major differences between these special conditions and the current CS 25.302 are as follows:

(1) Both the special conditions and CS 25.302 (and by reference Appendix K) specify the design load conditions to be considered. Effects of Systems on Structures, special conditions 2.a. and 3.b.i. clarify that, in some cases, different load conditions are to be considered due to other special conditions or equivalent-level-of-safety findings.

(2) Both the special conditions (see special condition 5, below) and CS 25.302 allow consideration of the probability of being in a dispatched configuration when assessing subsequent failures and potential ''continuation of flight'' loads. The special conditions, however, also allow using probability when assessing failures that induce loads at the ''time of occurrence,'' whereas CS 25.302 does not.

These special conditions contain the additional safety standards that the Administrator considers necessary to establish a level of safety equivalent to that established by the existing airworthiness standards.

Applicability

As discussed above, these special conditions are applicable to the Embraer Model ERJ 190–300 airplane. Should Embraer apply at a later date for a change to the type certificate to include another model incorporating the same novel or unusual design feature, these special conditions would apply to that model as well.

Conclusion

This action affects only a certain novel or unusual design feature on one model of airplane. It is not a rule of general applicability.

The substance of these special conditions has been published in the **Federal Register** for public comment in several prior instances and has been derived without substantive change from those previously issued. It is unlikely that prior public comment would result in a significant change from the substance contained herein. Therefore, the FAA has determined that prior public notice and comment are unnecessary and impracticable, and good cause exists for adopting these special conditions upon publication in the **Federal Register**. The FAA is requesting comments to allow interested persons to submit views that may not have been submitted in response to the prior opportunities for comment described above.

List of Subjects in 14 CFR Part 25

Aircraft, Aviation safety, Reporting and recordkeeping requirements.

The authority citation for these special conditions is as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701, 44702, 44704.

The Special Conditions

Accordingly, pursuant to the authority delegated to me by the Administrator, the following special conditions are issued as part of the type certification basis for Embraer Model ERJ 190–300 airplanes.

For airplanes equipped with systems that affect structural performance, either directly or as a result of a failure or malfunction, the influence of these systems and their failure conditions must be taken into account when showing compliance with the requirements of part 25, subparts C and D.

For airplanes equipped with flight-control systems, autopilots, stability-augmentation systems, load-alleviation systems, fuel-management systems, and other systems that either directly, or as a result of failure or malfunction, affect structural performance, the following criteria must be used for showing compliance. If these special conditions are used for other systems, it may be necessary to adapt the criteria to the specific system.

1. The criteria defined herein only address the direct structural consequences of the system responses and performance. They cannot be considered in isolation, but should be included in the overall safety evaluation of the airplane. These criteria may, in some instances, duplicate standards already established for this evaluation. These criteria are only applicable to structure the failure of which could prevent continued safe flight and landing. Specific criteria that define acceptable limits on handling characteristics or stability requirements, when operating in the system-degraded or inoperative mode, are not provided in these special conditions.

2. Depending upon the specific characteristics of the airplane, additional studies that go beyond the criteria provided in these special conditions may be required to demonstrate the airplane's capability to meet other realistic conditions, such as alternative gust or maneuver descriptions for an airplane equipped with a load-alleviation system.

3. The following definitions are applicable to these special conditions.

a. *Structural performance:* Capability of the airplane to meet the structural requirements of part 25.

b. *Flight limitations:* Limitations that can be applied to the airplane flight conditions following an in-flight occurrence, and that are included in the airplane flight manual (*e.g.,* speed limitations, avoidance of severe weather conditions, etc.).

c. *Operational limitations:* Limitations, including flight limitations, that can be applied to the airplane operating conditions before dispatch (*e.g.,* fuel, payload and master minimum-equipment list limitations).

d. *Probabilistic terms:* Terms such as probable, improbable, and extremely improbable, as used in these special conditions, are the same as those used in § 25.1309.

e. *Failure condition:* This term is the same as that used in § 25.1309. However, these special conditions apply only to system-failure conditions that affect the structural performance of the airplane (*e.g.,* system-failure conditions that induce loads, change the response of the airplane to inputs such as gusts or pilot actions, or lower flutter margins).

Effects of Systems on Structures

1. *General.* The following criteria will be used in determining the influence of a system and its failure conditions on the airplane structure.

2. *System fully operative.* With the system fully operative, the following apply:

a. Limit loads must be derived in all normal operating configurations of the system from all the limit conditions specified in part 25, subpart C (or defined by special conditions or findings of equivalent level of safety in lieu of those specified in subpart C), taking into account any special behavior of such a system or associated functions, or any effect on the structural performance of the airplane that may occur up to the limit loads. In particular, any significant nonlinearity (rate of displacement of control surface, thresholds, or any other system nonlinearities) must be accounted for in a realistic or conservative way when deriving limit loads from limit conditions.

b. The airplane must meet the strength requirements of part 25 (static strength, residual strength), using the specified factors to derive ultimate loads from the limit loads defined above. The effect of nonlinearities must be investigated beyond limit conditions to ensure that the behavior of the system presents no anomaly compared to the behavior below limit conditions. However, conditions beyond limit conditions need not be considered when it can be shown that the airplane has design features that will not allow it to exceed those limit conditions.

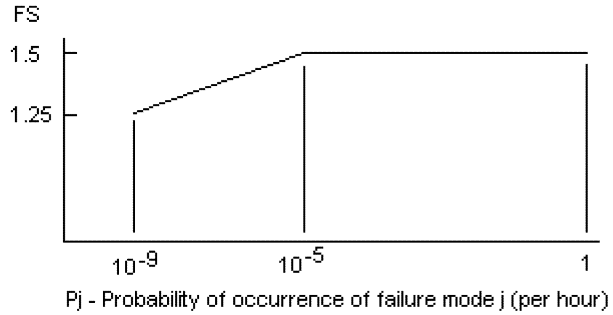
c. The airplane must meet the aeroelastic stability requirements of § 25.629.

3. *System in the failure condition.* For any system-failure condition not shown to be extremely improbable, the following apply:

a. At the time of occurrence. Starting from 1g level flight conditions, a realistic scenario, including pilot corrective actions, must be established to determine the loads occurring at the time of failure and immediately after the failure.

i. For static-strength substantiation, these loads, multiplied by an appropriate factor of safety that is related to the probability of occurrence of the failure, are ultimate loads to be considered for design. The factor of safety is defined in Figure 1, below.

Figure 1: Factor of safety (FS) at the time of occurrence



ii. For residual-strength substantiation, the airplane must be able to withstand two thirds of the ultimate loads defined in special condition 3.a.i. For pressurized cabins, these loads must be combined with the normal operating differential pressure.

iii. Freedom from aeroelastic instability must be shown up to the speeds defined in § 25.629(b)(2). For failure conditions that result in speeds beyond V_C/M_C, freedom from aeroelastic instability must be shown to increased speeds, so that the margins intended by § 25.629(b)(2) are maintained.

iv. Failures of the system that result in forced structural vibrations (oscillatory failures) must not produce loads that could result in detrimental deformation of primary structure.

b. For the continuation of the flight. For the airplane in the system-failed state, and considering any appropriate reconfiguration and flight limitations, the following apply:

i. The loads derived from the following conditions (or defined by special conditions or findings of equivalent level of safety in lieu of the following conditions) at speeds up to V_C/M_C (or the speed limitation prescribed for the remainder of the flight) must be determined:

1. The limit symmetrical maneuvering conditions specified in §§ 25.331 and 25.345.

2. the limit gust and turbulence conditions specified in §§ 25.341 and 25.345.

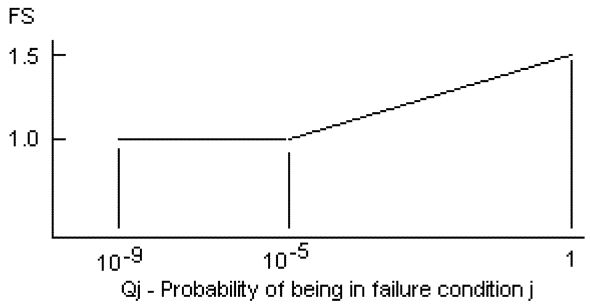
3. the limit rolling conditions specified in § 25.349, and the limit unsymmetrical conditions specified in §§ 25.367, and 25.427(b) and (c).

4. the limit yaw-maneuvering conditions specified in § 25.351.

5. the limit ground-loading conditions specified in §§ 25.473, 25.491, 25.493(d), and 25.503.

ii. For static-strength substantiation, each part of the structure must be able to withstand the loads in special condition 3.b.i., multiplied by a factor of safety depending on the probability of being in this failure state. The factor of safety is defined in Figure 2, below.

Figure 2: Factor of safety (FS) for continuation of flight



$Q_j = (T_j)(P_j)$

Where:

T_j = Average time spent in failure mode j (in hours)

P_j = Probability of occurrence of failure mode j (per hour)

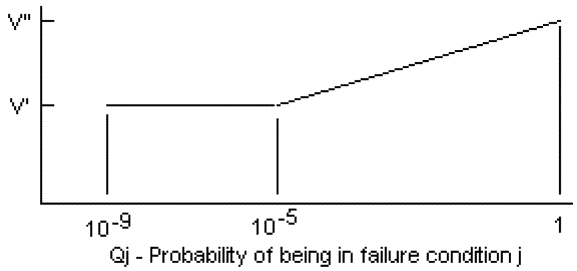
Note: If P_j is greater than 10^{-3} per flight hour, then a 1.5 factor of safety must be applied to all limit load conditions specified in part 25, subpart C.

iii. For residual-strength substantiation, the airplane must be able to withstand two-thirds of the ultimate loads defined in paragraph 3.b.ii. of these special conditions. For pressurized cabins, these loads must be combined with the normal operating differential pressure.

iv. If the loads induced by the failure condition have a significant effect on fatigue or damage tolerance, then their effects must be taken into account.

v. Freedom from aeroelastic instability must be shown up to a speed determined from Figure 3, below. Flutter clearance speeds V′ and V″ may be based on the speed limitation specified for the remainder of the flight using the margins defined by § 25.629(b).

Figure 3: Clearance speed



V′ = Clearance speed as defined by § 25.629(b)(2)

V″ = Clearance speed as defined by § 25.629(b)(1)

$Q_j = (T_j)(P_j)$

Where:

T_j = Average time spent in failure mode j (in hours)

P_j = Probability of occurrence of failure mode j (per hour)

Note: If P_j is greater than 10^{-3} per flight hour, then the flutter clearance speed must not be less than V″.

vi. Freedom from aeroelastic instability must also be shown up to V′ in Figure 3, above, for any probable system-failure condition, combined with any damage required or selected for investigation by § 25.571(b).

c. Consideration of certain failure conditions may be required by other sections of part 25 regardless of calculated system reliability. Where analysis shows the probability of these failure conditions to be less than 10^{-9} per flight hour, criteria other than those specified in this paragraph may be used for structural substantiation to show continued safe flight and landing.

4. *Failure indications.* For system-failure detection and indication, the following apply:

a. The system must be checked for failure conditions, not extremely improbable, that degrade the structural capability below the level required by part 25, or that significantly reduce the reliability of the remaining system. As far as reasonably practicable, the flightcrew must be made aware of these failures before flight. Certain elements of the control system, such as mechanical and hydraulic components, may use special periodic inspections, and electronic components may use daily checks, in lieu of detection and indication systems, to achieve the objective of this requirement. These certification-maintenance requirements must be limited to components that are not readily detectable by normal detection-and-indication systems, and where service history shows that inspections will provide an adequate level of safety.

b. The existence of any failure condition, not extremely improbable, during flight, that could significantly affect the structural capability of the airplane, and for which the associated reduction in airworthiness can be minimized by suitable flight limitations, must be signaled to the flightcrew. For example, failure conditions that result in a factor of safety between the airplane strength and the loads of part 25, subpart C below 1.25, or flutter margins below V″, must be signaled to the crew during flight.

5. *Dispatch with known failure conditions.* If the airplane is to be dispatched in a known system-failure condition that affects structural performance, or that affects the

reliability of the remaining system to maintain structural performance, then the provisions of these special conditions must be met, including the provisions of special condition 2 for the dispatched condition, and special condition 3 for subsequent failures. Expected operational limitations may be taken into account in establishing P_j as the probability of failure occurrence for determining the safety margin in Figure 1. Flight limitations and expected operational limitations may be taken into account in establishing Q_j as the combined probability of being in the dispatched failure condition and the subsequent failure condition for the safety margins in Figures 2 and 3. These limitations must be such that the probability of being in this combined failure state, and then subsequently encountering limit load conditions, is extremely improbable. No reduction in these safety margins is allowed if the subsequent system-failure rate is greater than 10^{-3} per flight hour.

Issued in Renton, Washington.

Victor Wicklund,

Manager, Transport Standards Branch, Aircraft Certification Service.

[FR Doc. 2017–16415 Filed 8–3–17; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[Docket No. USCG–2017–0715]

Drawbridge Operation Regulation; Isthmus Slough at Coos Bay, OR

AGENCY: Coast Guard, DHS.

ACTION: Notice of deviation from drawbridge regulation.

SUMMARY: The Coast Guard has issued a temporary deviation from the operating schedule that governs Oregon Department of Transportation's (ODOT) Isthmus Slough Bridge, mile 1.0 across Isthmus Slough at Coos Bay, OR. This deviation is necessary to accommodate painting and preservation and upgrading electrical systems. The deviation allows the bridge to operate in single leaf mode or one half of the bascule span, and reduce the vertical clearance of the non-functional leaf.

DATES: This deviation is effective from 6 a.m. on September 1, 2017 to 6 a.m. on February 26, 2018.

ADDRESSES: The docket for this deviation, USCG–2017–0715 is available at *http://www.regulations.gov.* Type the docket number in the ''SEARCH'' box and click ''SEARCH.'' Click on Open Docket Folder on the line associated with this deviation.

FOR FURTHER INFORMATION CONTACT: If you have questions on this temporary deviation, call or email Mr. Danny McReynolds, Bridge Management Specialist, Thirteenth Coast Guard District; telephone 206–220–7234, email *d13-pf-d13bridges@uscg.mil.*

SUPPLEMENTARY INFORMATION: ODOT, bridge owner, has requested a temporary deviation from the operating schedule for the Isthmus Slough Bridge, mile 1.0 across Isthmus Slough at Coos Bay, OR. The requested deviation is to accommodate painting and preservation and upgrading electrical systems. To facilitate this event, the double bascule bridge will operate in single leaf mode (half of the span), and reduce the vertical clearance of the non-functioning leaf. Isthmus Slough Bridge provides a vertical clearance of 28 feet in the closed-to-navigation position referenced to the vertical clearance above mean high water tide level. Ten feet of containment will be installed under the closed-to-navigation leaf only, and will reduce the vertical clearance to 18 feet. Vessels that do not require an opening may transit under the bridge at any time.

The normal operating schedule for the subject bridge is 33 CFR 117.879. This deviation allows the Isthmus Bridge to operate in single leaf, half opening, and reduce the vertical clearance of the non-functioning leaf by 10 feet to 18 feet; and need not open for maritime traffic from 6 a.m. on September 1, 2017 to 6 a.m. on February 26, 2018. The functional bascule leaf shall open on signal if at least 24 hours notice is given. Waterway usage on Isthmus Slough includes vessels ranging from small commercial tugs, commercial fishing vessels, police search and rescue to small pleasure craft.

Vessels able to pass through the bridge in the closed-to-navigation position may do so at any time. The bridge will be able open half of the double bascule in single leaf mode for emergencies as soon as possible, and there is no immediate alternate route for vessels to pass. The Coast Guard will inform the users of the waterway, through our Local and Broadcast Notices to Mariners, of the change in operating schedule for the bridges so that vessels can arrange their transits to minimize any impact caused by the temporary deviation.

In accordance with 33 CFR 117.35(e), the drawbridge must return to their regular operating schedule immediately at the end of the effective period of this temporary deviation. This deviation from the operating regulations is authorized under 33 CFR 117.35.

Dated: July 25, 2017.

Steven Michael Fischer,

Bridge Administrator, Thirteenth Coast Guard District.

[FR Doc. 2017–16425 Filed 8–3–17; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[Docket No. USCG–2017–0164]

Drawbridge Operation Regulation; Willamette River, Portland, OR

AGENCY: Coast Guard, DHS.

ACTION: Notice of deviation from drawbridge regulation; modification.

SUMMARY: The Coast Guard has modified a temporary deviation from the operating schedule that governs the Broadway Bridge across the Willamette River, mile 11.7, at Portland, OR. The modified deviation changes the period the bridge may operate the double bascule span one side at a time, single leaf, and reduce the vertical clearance to install and test new equipment.

DATES: This modified deviation is effective from 6 a.m. on August 16, 2017 to 6 p.m. on November 13, 2017.

ADDRESSES: The docket for this deviation, USCG–2017–0164, is available at *http://www.regulations.gov.* Type the docket number in the ''SEARCH'' box and click ''SEARCH.'' Click on Open Docket Folder on the line associated with this deviation.

FOR FURTHER INFORMATION CONTACT: If you have questions on this temporary deviation, call or email Mr. Danny McReynolds, Bridge Management Specialist, Thirteenth Coast Guard District; telephone 206–220–7234, email *d13-pf-d13bridges@uscg.mil.*

SUPPLEMENTARY INFORMATION: On March 15, 2017, the Coast Guard published a temporary deviation entitled ''Drawbridge Operation Regulation; Willamette River, Portland, OR.'' in the **Federal Register** (82 FR 13757). That temporary deviation, from 7 p.m. on May 26, 2017 to 6 a.m. on September 20, 2017, allows the bridge to operate the double bascule span one side at a time, single leaf, to install and test new equipment. The bridge owner, Multnomah County, has requested a modification of the currently published

deviation to cancel the dates before August 15, 2017, and extend the dates from 6 a.m. on August 16, 2017 to 6 p.m. on September 20, 2017; and from 6 a.m. on October 9, 2017, to 6 p.m. on November 13, 2017, in order to complete installation and test new equipment after delays with work contracts to the bridge deck.

The Broadway Bridge crosses the Willamette River at mile 11.7, and provides 90 feet of vertical clearance above Columbia River Datum 0.0 while in the closed-to-navigation position, and provides 125 feet of horizontal clearance with half the span open. The subject bridge operates in accordance with 33 CFR 117.897. This modified deviation allows the double bascule span of the Broadway Bridge to operate in single leaf mode for marine traffic. The deviation period allows the drawspan to operate single leaf and reduce the vertical clearance of the non-functional span from 90 feet to 80 feet during these dates: from 6 a.m. on August 16, 2017 to 6 p.m. on September 20, 2017; and from 6 a.m. on October 9, 2017, to 6 p.m. on November 13, 2017. The bridge shall operate in accordance to 33 CFR 117.897 at all other times. Waterway usage on this part of the Willamette River includes vessels ranging from commercial tug and barge to small pleasure craft. We have coordinated with the majority of known waterway users and there were no objections to this schedule.

Vessels able to pass through the bridge in the closed positions may do so at any time. The bridge will be able to open in single leaf for emergencies, and there is no immediate alternate route for vessels to pass. The Coast Guard will also inform the users of the waterways through our Local and Broadcast Notices to Mariners of the change in operating schedule for the bridge so that vessels can arrange their transits to minimize any impact caused by the modified deviation.

In accordance with 33 CFR 117.35(e), the drawbridge must return to its regular operating schedule immediately at the end of the effective period of this temporary deviation. This deviation from the operating regulations is authorized under 33 CFR 117.35.

Dated: July 31, 2017.

Steven Michael Fischer,

Bridge Administrator, Thirteenth Coast Guard District.

[FR Doc. 2017–16424 Filed 8–3–17; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG–2017–0677]

RIN 1625–AA00

Safety Zone; Mississippi River; New Orleans, LA

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary safety zone for navigable waters on the Mississippi River from mile marker (MM) 96 to MM 96.5 Above Head of Passes. The safety zone is needed to protect personnel, vessels, and the marine environment from potential hazards created by a fireworks display. Entry of vessels or persons into this zone is prohibited unless specifically authorized by the Captain of the Port, New Orleans (COTP).

DATES: This rule is effective from 7:30 p.m. through 8:30 p.m. on August 21, 2017.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to *http://www.regulations.gov,* type USCG–2017–0677 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 Commander (LCDR) Howard Vacco, Sector New Orleans, at (504) 365–2281 or *Howard.K.Vacco@uscg.mil.*

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

CFR Code of Federal Regulations
COTP Captain of the Port New Orleans
DHS Department of Homeland Security
FR Federal Register
NPRM Notice of proposed rulemaking
§ Section
U.S.C. United States Code

II. Background Information and Regulatory History

The Coast Guard is issuing this temporary rule without prior notice and opportunity to comment pursuant to authority under section 4(a) of the Administrative Procedure Act (APA) (5 U.S.C. 553(b)). This provision authorizes an agency to issue a rule without prior notice and opportunity to comment when the agency for good cause finds that those procedures are ''impracticable, unnecessary, or contrary to the public interest.'' Under 5 U.S.C. 553(b)(B), the Coast Guard finds that good cause exists for not publishing a notice of proposed rulemaking (NPRM) with respect to this rule because it is impracticable. We must establish this safety zone by August 21, 2017 and we lack sufficient time to provide a reasonable comment period and then consider those comments before issuing the rule. It is also contrary to the public interest as it would delay the safety measures necessary to protect life and property from the possible hazards associated with the fireworks display launched from the waterway. The impacts on navigation are expected to be minimal as the safety zone will only be in effect for a short duration of one hour. The Coast Guard will notify the public and maritime community that the safety zone will be in effect and of its enforcement periods via Broadcast Notice to Mariners (BNM) and Marine Safety Information Bulletin (MSIB).

Under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this rule effective less than 30 days after publication in the **Federal Register**. Delaying the effective date of this rule is contrary to public interest because it would delay the safety measures necessary to respond to potential safety hazards associated with the fireworks display.

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 New Orleans (COTP) has determined that potential hazards associated with a fireworks display on August 21, 2017 will be a safety concern for anyone on the navigable waterways within a one-half mile range of the fireworks. This rule is needed to protect personnel, vessels, and the marine environment in the navigable waters within the safety zone while the fireworks are being launched.

IV. Discussion of the Rule

This rule establishes a safety zone from 7:30 p.m. through 8:30 p.m. on August 21, 2017. The safety zone will cover all navigable waters from mile marker 96 to 96.5 Above Head of Passes on the Mississippi River. The duration of the zone is intended to protect personnel, vessels, and the marine environment in these navigable waters from the hazards of the fireworks. No vessel or person will be permitted to enter the safety zone without obtaining permission from the COTP or a designated representative.

V. Regulatory Analyses

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

A. Regulatory Planning and Review

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

This regulatory action determination is based on the size, location, duration, and time-of-year of the safety zone. This safety zone will impact a small designated area of the Mississippi River for 1 hour. Moreover, the Coast Guard will issue BNMs via VHF–FM Channel 16 about the zone and the rule allows vessels to seek permission to enter the zone.

B. Impact on Small Entities

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

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

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

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

C. Collection of Information

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

D. Federalism and Indian Tribal Governments

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

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

E. Unfunded Mandates Reform Act

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

F. Environment

We have analyzed this rule under Department of Homeland Security 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 creating a safety zone lasting one hour that will prohibit entry and navigating between mile marker 96 to 96.5, Above Head of Passes on the Mississippi River. It is categorically excluded from further review under paragraph 34(g) of Figure 2–1 of the Commandant Instruction. A Record of Environmental Consideration supporting this determination is available in the docket where indicated under **ADDRESSES**.

G. Protest Activities

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

List of Subjects in 33 CFR Part 165

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, and 160.5; Department of Homeland Security Delegation No. 0170.1.

■ 2. Add § 165.T08–0677 to read as follows:

§ 165.T08–0677 Safety Zone; Mississippi River, New Orleans, LA.

(a) *Location.* The following area is a safety zone: All navigable waters of the Mississippi River between mile marker 96 and 96.5 Above Head of Passes.

(b) *Effective period.* This rule is effective from 7:30 p.m. through 8:30 p.m. on August 21, 2017.

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

(2) Vessels requiring entry into this safety zone must request permission from the COTP or a designated representative. They may be contacted on VHF–FM Channel 16 or 67.

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

(d) *Information broadcasts.* The COTP or a designated representative will inform the public through Broadcast Notices to Mariners of any changes in the planned schedule.

Dated: July 31, 2017.

Wayne R. Arguin,

Captain, U.S. Coast Guard, Captain of the Port New Orleans.

[FR Doc. 2017–16436 Filed 8–3–17; 8:45 am]

BILLING CODE 9110–04–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 62

[EPA–R08–OAR–2017–0171; FRL–9965–78–Region 8]

Approval and Promulgation of State Plans for Designated Facilities and Pollutants: Colorado, Montana, North Dakota, South Dakota, Utah, and Wyoming; Negative Declarations

AGENCY: Environmental Protection Agency (EPA).

ACTION: Withdrawal of direct final rule.

SUMMARY: The Environmental Protection Agency (EPA) is withdrawing a direct final rule published on June 5, 2017, because one adverse comment was received during the public comment period. The withdrawn rule pertained to the EPA's receipt and approval of 20 negative declaration letters from EPA Region 8 states. These letters of negative declaration are statements by the state certifying the absence of designated facilities of a certain solid waste incinerator category or class within its jurisdiction, which obviates the statutory requirement for the state to develop a Clean Air Act (CAA) section 111(d)/129 State plan for the regulation of designated facilities of that particular category or class.

DATES: Effective August 3, 2017, the direct final rule published at 82 FR 25734, June 5, 2017 is withdrawn.

FOR FURTHER INFORMATION CONTACT: Gregory Lohrke, (303) 312–6396, *lohrke.gregory@epa.gov.*

SUPPLEMENTARY INFORMATION: On June 5, 2017, the EPA published a direct final rule (82 FR 25734) approving several negative declarations submitted by Region 8 states, certifying the absence of designated facilities regulated under various Emissions Guidelines found in 40 CFR part 60. The promulgation of each negative declaration was to serve in lieu of a CAA section 111(d)/129 State plan, given the declared absence of facilities that would require such a State plan. The direct final rule was published without prior proposal because the EPA anticipated no adverse comments on a noncontroversial action. The direct final rule stated that if the action received adverse comment on or before July 5, 2017, the EPA would publish a timely withdrawal in the **Federal Register**. The EPA received one adverse comment and is accordingly withdrawing the direct final rule. In a separate, subsequent final rulemaking action, the EPA will address the comment received.

List of Subjects in 40 CFR Part 62

Environmental protection, Administrative practice and procedure, Air pollution control, Commercial industrial solid waste incineration, Intergovernmental relations, Municipal solid waste combustion, Other solid waste incineration, Reporting and recordkeeping requirements.

Dated: July 28, 2017.

Debra H. Thomas,

Acting Regional Administrator, Region 8.

■ Accordingly, the amendments to 40 CFR part 62, subpart G, subpart BB, subpart JJ, subpart QQ, subpart TT, and subpart ZZ, published in the **Federal Register** on June 5, 2017 (82 FR 25734), are withdrawn as of August 3, 2017.

[FR Doc. 2017–16492 Filed 8–3–17; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2016–0507; FRL–9963–58]

Beta Cyclodextrin, Methyl Ethers; Exemption From the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes an exemption from the requirement of a tolerance for residues of beta cyclodextrin, methyl ethers (CAS Reg. No. 128446–36–6) when used as an inert ingredient (stabilizer and solvent) in pesticide formulations applied to growing crops pre-harvest limited to a maximum concentration of 40% by weight in the pesticide formulation. Lewis and Harrison, LLC, on behalf of Wacker Chemie AG submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), requesting establishment of an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of beta cyclodextrin, methyl ethers that result from applications of pesticides consistent with the conditions in EPA regulations.

DATES: This regulation is effective August 4, 2017. Objections and requests for hearings must be received on or before October 3, 2017, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA–HQ–OPP–2016–0507, is available at *http://www.regulations.gov* or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave. NW., Washington, DC 20460–0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the OPP Docket is (703) 305–5805. Please review the visitor instructions and additional information about the docket available at *http://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: Michael Goodis, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200

Pennsylvania Ave. NW., Washington, DC 20460–0001; main telephone number: (703) 305–7090; email address: *RDFRNotices@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

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

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

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

You may access a frequently updated electronic version of 40 CFR part 180 through the Government Printing Office's e-CFR site at *http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl.*

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

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–OPP–2016–0507 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before October 3, 2017. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA–HQ–OPP–2016–0507, by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.
- *Mail:* OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001.
- *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at *http://www.epa.gov/dockets/contacts.html.*

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

II. Petition for Exemption

In the **Federal Register** of February 7, 2017 (82 FR 9555) (FRL–9956–86), EPA issued a document pursuant to FFDCA section 408, 21 U.S.C. 346a, announcing the filing of a pesticide petition (IN–10964) by Lewis and Harrison, LLC (122 C St. NW., Suite 505, Washington, DC 20001), on behalf of Wacker Chemie AG (Hanns-Seidel-Platz 4, D–81737 Munich, Germany). The petition requested that 40 CFR 180.920 be amended by establishing an exemption from the requirement of a tolerance for residues of beta cyclodextrin, methyl ethers (CAS Reg. No. 128446–36–6) when used as an inert ingredient (stabilizer/solvent) in pesticide formulations applied to growing crops pre-harvest, limited to 40% by weight in the pesticide formulation. That document referenced a summary of the petition prepared by Lewis and Harrison, LLC, on behalf of Wacker Chemie AG, the petitioner, which is available in the docket, *http://www.regulations.gov.* There were no comments received in response to the notice of filing.

The Agency is establishing an exemption from the requirement of a tolerance as requested, but is using the chemical abstract index name ''beta-cyclodextrin, methyl ethers'', the assigned formal name rather than ''methyl-beta-cyclodextrin'', the common name.

III. Inert Ingredient Definition

Inert ingredients are all ingredients that are not active ingredients as defined in 40 CFR 153.125 and include, but are not limited to, the following types of ingredients (except when they have a pesticidal efficacy of their own): Solvents such as alcohols and hydrocarbons; surfactants such as polyoxyethylene polymers and fatty acids; carriers such as clay and diatomaceous earth; thickeners such as carrageenan and modified cellulose; wetting, spreading, and dispersing agents; propellants in aerosol dispensers; microencapsulating agents; and emulsifiers. The term ''inert'' is not intended to imply nontoxicity; the ingredient may or may not be chemically active. Generally, EPA has exempted inert ingredients from the requirement of a tolerance based on the low toxicity of the individual inert ingredients.

IV. Aggregate Risk Assessment and Determination of Safety

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

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

inert ingredient, an exemption from the requirement of a tolerance may be established.

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

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered their validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. Specific information on the studies received and the nature of the adverse effects caused by beta cyclodextrin, methyl ethers as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies are discussed in this unit.

All studies are conducted with beta cyclodextrin, methyl ethers except the developmental/reproduction toxicity studies which are conducted with beta-cyclodextrin (β-CD) and 2-hydroxypropyl-beta-cyclodextrin (HP-β-CD). These chemicals are structurally similar to beta cyclodextrin, methyl ethers and are considered suitable surrogates. A quantitative structural-activity relationship (QSAR) analysis demonstrates that results are nearly identical for these chemicals; therefore, data from the developmental/reproduction toxicity studies conducted with β-CD and HP-β-CD are used to assess potential developmental/reproduction toxicity from beta cyclodextrin, methyl ethers exposure.

The acute oral toxicity is low in rats and mice for beta cyclodextrin, methyl ethers. The lethal dose (LD_{50}) is >8,000 milligrams/kilogram (mg/kg) in acute oral toxicity studies in the rat and mouse. Beta cyclodextrin, methyl ethers is not irritating to the skin in the rabbit. It is moderately irritating to the eyes in rabbits. Acute inhalation toxicity is low; the lethal concentration (LC_{50}) is >2.95 milligram/liter (mg/L) (equivalent to 398 mg/kg). Beta cyclodextrin, methyl ethers is not a dermal sensitizer in the guinea pig maximization test.

Beta cyclodextrin, methyl ethers administered via the diet for 28 days causes tubular degeneration of the renal cortex at 1,000 milligrams/kilogram/day (mg/kg/day). The no-observed-adverse-effect level (NOAEL) is 300 mg/kg/day.

No fetal susceptibility was observed in any of the developmental and reproduction toxicity studies. Following oral administration of beta-cyclodextrin in rats and rabbits, no developmental toxicity was observed at doses as high as 5,000 mg/kg/day and 600 mg/kg/day, respectively. No maternal toxicity was observed at doses as high as 2,500 mg/kg/day and 600 mg/kg/day in rats and rabbits, respectively. Similarly, no developmental or maternal toxicity was observed in rats following oral exposure to doses of 2-hydroxypropyl-beta-cyclodextrin as high as 5,000 mg/kg/day and in rabbits following oral exposure to doses as high as 500 mg/kg/day. Following intravenous administration of 2-hydroxypropyl-beta-cyclodextrin to rats, slight maternal toxicity was observed at 400 mg/kg/day (with a NOAEL at 100 mg/kg/day), but no developmental toxicity was observed. No maternal or developmental toxicity was observed in rabbits exposed to doses of 2-hydroxypropyl-beta-cyclodextrin at 400 mg/kg/day, the highest dose tested. In the three-generation reproduction toxicity study in rats, no effects were observed in parental or offspring animals at doses up to 1,099 mg/kg/day beta-cyclodextrin. No reproduction effects were observed up to 2,277 mg/kg/day.

Beta cyclodextrin, methyl ethers administered for 26 weeks via gavage causes tubular vacuolation in the kidney at 500 mg/kg/day. The NOAEL is 100 mg/kg/day. The chronic reference dose (cRfD) is based on this study.

Carcinogenicity studies with beta cyclodextrin, methyl ethers are not available; however, a Deductive Estimation of Risk from Existing Knowledge (Derek) Nexus structural alert analysis was conducted with beta cyclodextrin, methyl ethers and indicated no structural alerts for carcinogenicity or mutagenicity. Therefore, beta cyclodextrin, methyl ethers is not expected to be carcinogenic.

All available mutagenicity studies (Ames tests, gene mutation, chromosomal aberrations, unscheduled DNA synthesis and micronucleus tests) were negative; therefore, beta cyclodextrin, methyl ethers is not mutagenic.

Although neurotoxicity and immunotoxicity studies are not available for review, evidence of neurotoxicity and immunotoxicity is not observed in the submitted studies.

Beta cyclodextrin, methyl ethers is not metabolized and very little is absorbed. Following oral exposure, it is mostly excreted in the feces and 0.92% is excreted in the urine. 0.97–0.92% of an orally administered dose is absorbed. A distribution study shows that beta cyclodextrin, methyl ethers is found along the gastrointestinal tract, in the kidney and bladder. Dermal absorption is estimated to be 0.4% in 126 hours in rats.

B. Toxicological Points of Departure/Levels of Concern

Once a pesticide's toxicological profile is determined, EPA identifies toxicological points of departure (POD) and levels of concern to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment. PODs are developed based on a careful analysis of the doses in each toxicological study to determine the dose at which no adverse effects are observed (the NOAEL) and the lowest dose at which adverse effects of concern are identified (the LOAEL). Uncertainty/safety factors are used in conjunction with the POD to calculate a safe exposure level—generally referred to as a population-adjusted dose (PAD) or a reference dose (RfD)—and a safe margin of exposure (MOE). For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see *http://www.epa.gov/pesticides/factsheets/riskassess.htm.*

A summary of the toxicological endpoints for beta cyclodextrin, methyl ethers used for human risk assessment is shown in Table 1 of this unit.

TABLE 1—SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR BETA CYCLODEXTRIN, METHYL ETHERS FOR USE IN HUMAN RISK ASSESSMENT

Exposure/scenario	Point of departure and uncertainty/ safety factors	RfD, PAD, LOC for risk assessment	Study and toxicological effects
Acute dietary (General population including infants and children).	An acute effect was not found in the database therefore an acute dietary assessment is not necessary.		
Chronic dietary (All populations)	NOAEL = 100 mg/kg/day. UF_A = 10x UF_H = 10x FQPA SF = 1x	Chronic RfD = 1.00 mg/kg/day. cPAD = 1.00 mg/kg/day	26-week Oral Toxicity Study-Rat LOAEL = 500 mg/kg/day based on tubular degeneration in the kidneys.
Incidental oral short-term (1 to 30 days).	NOAEL= 300 mg/kg/day. UF_A = 10x UF_H = 10x FQPA SF = 1x	LOC for MOE = 100	28-Day Oral Toxicity Study-Rat LOAEL = 1,000 mg/kg/day based on tubular vacuolation in the kidneys.
Incidental oral intermediate-term (1 to 6 months).	NOAEL = 100 mg/kg/day. UF_A = 10x UF_H = 10x FQPA SF = 1x	LOC for MOE = 100	26-week Oral Toxicity Study-Rat LOAEL = 500 mg/kg/day based on tubular degeneration in the kidneys.
Dermal short-term (1 to 30 days).	NOAEL = 300 mg/kg/day (dermal absorption rate = 0.4%). UF_A = 10x UF_H = 10x FQPA SF = 1x	LOC for MOE = 100	28-Day Oral Toxicity Study-Rat LOAEL = 1,000 mg/kg/day based on tubular vacuolation in the kidneys.
Dermal intermediate-term (1 to 6 months).	NOAEL= 100 mg/kg/day (dermal absorption rate = 0.4%). UF_A = 10x UF_H = 10x FQPA SF = 1x	LOC for MOE = 100	26-week Oral Toxicity Study-Rat LOAEL = 500 mg/kg/day based on tubular degeneration in the kidneys.
Inhalation short-term (1 to 30 days).	NOAEL= 300 mg/kg/day (inhalation absorption rate = 100%). UF_A = 10x UF_H = 10x FQPA SF = 1x	LOC for MOE = 100	28-Day Oral Toxicity Study-Rat LOAEL = 1,000 mg/kg/day based on tubular vacuolation in the kidneys.
Inhalation intermediate-term (1 to 6 months).	NOAEL = 100 mg/kg/day (inhalation absorption rate = 100%). UF_A = 10x UF_H = 10x FQPA SF = 1x	LOC for MOE = 100	26-week Oral Toxicity Study-Rat LOAEL = 500 mg/kg/day based on tubular degeneration in the kidneys.
Cancer (Oral, dermal, inhalation).	Based on a Derek structural alert analysis and the lack of mutagenicity, beta cyclodextrin, methyl ethers is considered not likely to be carcinogenic.		

FQPA SF = Food Quality Protection Act Safety Factor. LOAEL = lowest-observed-adverse-effect-level. LOC = level of concern. mg/kg/day = milligram/kilogram/day. MOE = margin of exposure. NOAEL = no-observed-adverse-effect-level. PAD = population adjusted dose (a = acute, c = chronic). RfD = reference dose. UF = uncertainty factor. UF_A = extrapolation from animal to human (interspecies). UF_{DB} = to account for the absence of data or other data deficiency. UF_H = potential variation in sensitivity among members of the human population (intraspecies). UF_L = use of a LOAEL to extrapolate a NOAEL. UF_S = use of a short-term study for long-term risk assessment.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to beta cyclodextrin, methyl ethers, EPA considered exposure under the requested exemption from the requirement of a tolerance. EPA assessed dietary exposures from beta cyclodextrin, methyl ethers in food as follows:

i. Dietary exposure (food and drinking water) to beta cyclodextrin, methyl ethers can occur following ingestion of foods with residues from treated crops. Because no adverse effects attributable to a single exposure of beta cyclodextrin, methyl ethers are seen in the toxicity databases, an acute dietary risk assessment is not necessary. For the chronic dietary risk assessment, EPA used the Dietary Exposure Evaluation Model software with the Food Commodity Intake Database (DEEM–FCID™, Version 3.16, and food consumption information from the U.S. Department of Agriculture's (USDA's) 2003–2008 National Health and Nutrition Examination Survey, What We Eat in America (NHANES/WWEIA). As to residue levels in food, no residue data were submitted for beta cyclodextrin, methyl ethers. In the absence of specific residue data, EPA has developed an approach which uses surrogate information to derive upper

bound exposure estimates for the subject inert ingredient. Upper bound exposure estimates are based on the highest tolerance for a given commodity from a list of high use insecticides, herbicides, and fungicides. One hundred percent crop treated was assumed, default processing factors, and tolerance-level residues for all foods and use limitations of not more than 40% by weight in pesticide formulations. A complete description of the general approach taken to assess inert ingredient risks in the absence of residue data is contained in the memorandum entitled ''Alkyl Amines Polyalkoxylates (Cluster 4): Acute and Chronic Aggregate (Food and Drinking Water) Dietary Exposure and Risk Assessments for the Inerts,'' (D361707, S. Piper, 2/25/09) and can be found at *http://www.regulations.gov* in docket ID number EPA–HQ–OPP–2008–0738.

2. *Dietary exposure from drinking water.* For the purpose of the screening level dietary risk assessment to support this request for an exemption from the requirement of a tolerance for beta cyclodextrin, methyl ethers, a conservative drinking water concentration value of 100 parts per billion (ppb) based on screening level modeling was used to assess the contribution to drinking water for the chronic dietary risk assessments for parent compound. These values were directly entered into the dietary exposure model.

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

Beta cyclodextrin, methyl ethers may be used in inert ingredients in products that are registered for specific uses that may result in residential exposure, such as pesticides used in and around the home. The Agency conducted an assessment to represent conservative residential exposure by assessing beta cyclodextrin, methyl ethers in pesticide formulations (outdoor scenarios) and in disinfectant-type uses (indoor scenarios). The Agency's assessment of adult residential exposure combines high end dermal and inhalation handler exposure from liquids/backpack sprayer/home garden with a high end post application dermal exposure from contact with treated lawns. The Agency's assessment of children's residential exposure includes total post-application exposures associated with contact with treated surfaces (dermal and hand-to-mouth exposures).

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

EPA has not found beta cyclodextrin, methyl ethers to share a common mechanism of toxicity with any other substances, and beta cyclodextrin, methyl ethers does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that beta cyclodextrin, methyl ethers does not have a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA's Web site at *http://www.epa.gov/pesticides/cumulative.*

D. Safety Factor for Infants and Children

1. *In general.* Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the Food Quality Protection Act (FQPA) Safety Factor (SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity.* The toxicity database for beta cyclodextrin, methyl ethers contains developmental and 3-generation reproduction toxicity studies conducted with surrogate chemicals. Increased fetal susceptibility is not observed in any of the studies: The only fetal effects observed (slight embryotoxicity following oral exposure in developmental toxicity study in rabbits to 2-hydroxypropyl-beta-cyclodextrin at doses of 1,000 mg/kg/day) occurred in the presence of slight maternal toxicity (NOAEL of 500 mg/kg/day). In other studies involving oral exposure to beta-cyclodextrin and to 2-hydroxypropyl-beta-cyclodextrin in rats and rabbits, no adverse effects of statistical significance were observed in fetuses. In the three-generation reproduction toxicity study in rats, no effects were observed in parental or offspring animals at doses up to 1,099 mg/kg/day beta-cyclodextrin. No reproduction effects were observed up to 2,277 mg/kg/day.

3. *Conclusion.* The toxicity database for beta cyclodextrin, methyl ethers contains subchronic, developmental, 3-generation reproduction toxicity and mutagenicity studies. Although there are no neurotoxicity or immunotoxicity studies, there is no need to retain the FQPA 10X safety factor because there is no indication of potential neurotoxicity or immunotoxicity in the available studies. Also, there is no need to retain the FQPA 10X safety factor for lack of an inhalation study because baseline inhalation margin of exposure (MOE) ranges from 86000–1400000 and more than adequately surpass the Agency's level of concern of MOEs<100 or MOEs<1,000 if an additional 10X were applied. In addition, the Agency used conservative exposure estimates, with 100 percent crop treated, tolerance-level residues, conservative drinking water modeling numbers, and a conservative assessment of potential residential exposure for infants and children. Based on the adequacy of the toxicity database and the conservative nature of the exposure assessment and the lack of concern for prenatal and postnatal sensitivity, the Agency has concluded that there is reliable data to determine that infants and children will be safe if the FQPA SF of 10x is reduced to 1x.

E. Aggregate Risks and Determination of Safety

EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing aggregate exposure estimates to the acute PAD (aPAD) and chronic PAD (cPAD). For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure. Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate PODs to ensure that an adequate MOE exists.

1. *Acute risk.* An acute aggregate risk assessment takes into account acute exposure estimates from dietary consumption of food and drinking water. No adverse effect resulting from a single oral exposure was identified and no acute dietary endpoint was selected. Therefore, beta cyclodextrin, methyl ethers is not expected to pose an acute risk.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to beta

cyclodextrin, methyl ethers from food and water will utilize 56.6% of the cPAD for children 1–2 years old, the population group receiving the greatest exposure.

3. *Short-term risk.* Short-term aggregate exposure takes into account short-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level).

Beta cyclodextrin, methyl ethers may be used as an inert ingredient in pesticide products that are registered for uses that could result in short-term residential exposure, and the Agency has determined that it is appropriate to aggregate chronic exposure through food and water with short-term residential exposures to beta cyclodextrin, methyl ethers.

Using the exposure assumptions described above for short-term exposures, EPA has concluded the combined short-term food, water, and residential exposures result in aggregate MOEs of 1910 for both adult males and females respectively. EPA has concluded the combined short-term aggregated food, water, and residential pesticide exposures result in an aggregate MOE of 500 for children. Because EPA's level of concern for beta cyclodextrin, methyl ethers is a MOE of 100 or below, these MOEs are not of concern.

4. *Intermediate-term risk.* Intermediate-term aggregate exposure takes into account intermediate-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level).

Beta cyclodextrin, methyl ethers may be used as an inert ingredient in pesticide products that are registered for uses that could result in intermediate-term residential exposure, and the Agency has determined that it is appropriate to aggregate chronic exposure through food and water with intermediate-term residential exposures to beta cyclodextrin, methyl ethers.

Using the exposure assumptions described above for intermediate-term exposures, EPA has concluded that the combined intermediate-term food, water, and residential exposures result in aggregate MOEs of 650 for adult males and females. EPA has concluded the combined intermediate-term aggregated food, water, and residential exposures result in an aggregate MOE of 170 for children. Because EPA's level of concern for beta cyclodextrin, methyl ethers is a MOE of 100 or below, these MOEs are not of concern.

5. *Aggregate cancer risk for U.S. population.* Based on the lack of structural alerts in a DEREK structural alert analysis and the lack of mutagenicity, beta cyclodextrin, methyl ethers is not expected to pose a cancer risk to humans.

6. *Determination of safety.* Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population, or to infants and children from aggregate exposure to beta cyclodextrin, methyl ethers residues.

V. Other Considerations

A. Analytical Enforcement Methodology

An analytical method is not required for enforcement purposes since the Agency is not establishing a numerical tolerance for residues of beta cyclodextrin, methyl ethers in or on any food commodities. EPA is establishing limitations on the amount of beta cyclodextrin, methyl ethers that may be used in pesticide formulations applied to growing crops. These limitations will be enforced through the pesticide registration process under the Federal Insecticide, Fungicide, and Rodenticide Act (''FIFRA''), 7 U.S.C. 136 *et seq.* EPA will not register any pesticide formulation for use on growing crops pre-harvest for sale or distribution that exceeds 40% by weight of beta cyclodextrin, methyl ethers unless additional data are submitted.

VI. Conclusions

Therefore, an exemption from the requirement of a tolerance is established under 40 CFR 180.920 for beta cyclodextrin, methyl ethers (CAS Reg. No. 128446–36–6) when used as an inert ingredient (stabilizer and solvent) in pesticides applied to growing crops pre-harvest limited to a maximum concentration of 40% by weight in the pesticide formulation.

VII. Statutory and Executive Order Reviews

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

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

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

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

VIII. Congressional Review Act

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

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

List of Subjects in 40 CFR Part 180

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

Dated: June 22, 2017.

Michael L. Goodis,

Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

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

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

■ 2. In § 180.920, add alphabetically the entry ''Beta Cyclodextrin, Methyl Ethers'' to the table to read as follows:

§ 180.920 Inert ingredients used pre-harvest; exemptions from the requirement of a tolerance.

* * * * *

Inert ingredients	Limits	Uses
* * * * * * *		
Beta Cyclodextrin, Methyl Ethers (CAS Reg. No. 128446–36–6)	40% by weight	Stabilizer and solvent.
* * * * * * *		

[FR Doc. 2017–16373 Filed 8–3–17; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 300

[Docket No. 170329334–7665–01]

RIN 0648–BG78

International Fisheries; Western and Central Pacific Fisheries for Highly Migratory Species; Bigeye Tuna Catch Limits in Longline Fisheries for 2017

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

ACTION: Interim rule; request for comments.

SUMMARY: NMFS issues regulations under authority of the Western and Central Pacific Fisheries Convention Implementation Act (WCPFC Implementation Act) to modify a limit on the amount of bigeye tuna (*Thunnus obesus*) that may be captured by U.S. longline vessels in the western and central Pacific Ocean (WCPO), to 3,138 metric tons (mt) for calendar year 2017. The limit does not apply to vessels in the longline fisheries of American Samoa, Guam, or the Commonwealth of the Northern Mariana Islands (CNMI). Once the limit of 3,138 mt is reached in 2017, retaining, transshipping, or landing bigeye tuna caught in the area of application of the Convention on the Conservation and Management of Highly Migratory Fish Stocks in the Western and Central Pacific Ocean (Convention), which comprises the majority of the WCPO, will be prohibited for the remainder of the calendar year, with certain exceptions. This action is necessary for the United States to satisfy its obligations under the Convention, to which it is a Contracting Party.

DATES: Effective on August 4, 2017. Comments must be submitted in writing by September 5, 2017.

ADDRESSES: You may submit comments on this document, identified by NOAA–NMFS–2017–0085, and the regulatory impact review (RIR) prepared for the interim rule, by either of the following methods:

- *Electronic submission:* Submit all electronic public comments via the Federal e-Rulemaking Portal.

1. Go to *www.regulations.gov/#!docketDetail;D=NOAA-NMFS-2017-0085,*

2. Click the ''Comment Now!'' icon, complete the required fields, and

3. Enter or attach your comments.

- OR -

- *Mail:* Submit written comments to Michael D. Tosatto, Regional Administrator, NMFS, Pacific Islands Regional Office (PIRO), 1845 Wasp Blvd., Building 176, Honolulu, HI 96818.

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

Copies of the RIR, and the programmatic environmental assessment and supplemental information report prepared for National Environmental Policy Act purposes are available at *www.regulations.gov* or may be obtained from Michael D. Tosatto, Regional Administrator, NMFS PIRO (see address above)

FOR FURTHER INFORMATION CONTACT: Rini Ghosh, NMFS PIRO, 808–725–5033.

SUPPLEMENTARY INFORMATION:

Background on the Convention

A map showing the boundaries of the area of application of the Convention (Convention Area), which comprises the majority of the WCPO, can be found on the WCPFC Web site at: *www.wcpfc.int/doc/convention-area-map.* The Convention focuses on the conservation and management of highly migratory species (HMS) and the management of fisheries for HMS. The objective of the Convention is to ensure, through effective management, the long-term conservation and sustainable use of HMS in the WCPO. To accomplish this objective, the Convention established the Commission on the Conservation and Management of Highly Migratory Fish Stocks in the Western and Central Pacific Ocean (Commission or WCPFC). The Commission includes Members, Cooperating Non-members, and Participating Territories (hereafter, collectively ''Members''). The United States is a Member. American Samoa, Guam, and the CNMI are Participating Territories.

As a Contracting Party to the Convention and a Member of the Commission, the United States is obligated to implement the decisions of the Commission. The WCPFC Implementation Act (16 U.S.C. 6901 *et seq.*) authorizes the Secretary of Commerce, in consultation with the

Secretary of State and the Secretary of the Department in which the United States Coast Guard is operating (currently the Department of Homeland Security), to promulgate such regulations as may be necessary to carry out the obligations of the United States under the Convention, including implementation of the decisions of the Commission. The WCPFC Implementation Act further provides that the Secretary of Commerce shall ensure consistency, to the extent practicable, of fishery management programs administered under the WCPFC Implementation Act and the Magnuson-Stevens Fishery Conservation and Management Act (MSA; 16 U.S.C. 1801 *et seq.*), as well as other specific laws (see 16 U.S.C. 6905(b)). The Secretary of Commerce has delegated the authority to promulgate regulations under the WCPFC Implementation Act to NMFS.

WCPFC Decision on Tropical Tunas

At its Thirteenth Regular Session, in December 2016, the WCPFC adopted Conservation and Management Measure (CMM) 2016–01, ''Conservation and Management Measure for Bigeye, Yellowfin and Skipjack Tuna in the Western and Central Pacific Ocean.'' CMM 2016–01 is the most recent in a series of CMMs for the management of tropical tuna stocks under the purview of the Commission. CMM 2016–01 maintains the provisions of its predecessor, CMM 2015–01. These and other CMMs are available at: *www.wcpfc.int/conservation-and-management-measures.*

The stated general objective of CMM 2016–01 and several of its predecessor CMMs is to ensure that the stocks of bigeye tuna (*Thunnus obesus*), yellowfin tuna (*Thunnus albacares*), and skipjack tuna (*Katsuwonus pelamis*) in the WCPO are, at a minimum, maintained at levels capable of producing their maximum sustainable yield as qualified by relevant environmental and economic factors. The CMM includes specific objectives for each of the three stocks: For each, the fishing mortality rate is to be reduced to or maintained at levels no greater than the fishing mortality rate associated with maximum sustainable yield.

CMM 2016–01 went into effect February 2017, and is generally applicable for 2017. The CMM includes provisions for purse seine vessels, longline vessels, and other types of vessels that fish for HMS. The CMM's provisions for longline vessels include catch limits for bigeye tuna and a general provision not to increase catches of yellowfin tuna.

The Action

In 2016, NMFS established catch limits for bigeye tuna that may be captured in the Convention Area by longline gear and retained on board by fishing vessels of the United States for calendar years 2016 and 2017, putting into place provisions of CMM 2015–01, the predecessor to CMM 2016–01 (81 FR 41239). The limit for 2016 was set at 3,554 mt and the limit for 2017 was set at 3,345 mt. (*Id.*). As in CMM 2015–01, under paragraphs 40–42 of CMM 2016–01, Commission members are to limit catches by their longline vessels of bigeye tuna in the Convention Area to specified levels in 2017. Under CMM 2016–01, the applicable limit for the United States in 2017 continues to be 3,345 mt. In addition, paragraph 40 of CMM 2016–01 reiterates the provision of CMM 2015–01 that states that any catch overage in a given year shall be deducted from the catch limit for the following year. The Commission has not adopted limits for the longline fisheries of any of the U.S. Participating Territories, American Samoa, Guam, and the CNMI.

This interim rule is limited to implementing the 2017 calendar year longline bigeye tuna catch limit for U.S. fisheries in the Convention Area, as mandated under CMM 2016–01 which continues the relevant provisions adopted by CMM 2015–01. As stated above, the Commission-adopted limit for 2017 continues to be 3,345 mt less any overage of the limit applicable in 2016. The limit for 2016 was 3,554 mt (*see* 81 FR 41239). There was an overage of 207 mt in 2016, so the limit for 2017 is 3,138 mt. This interim rule adjusts the 2017 limit from the established 3,345 mt to 3,138 mt.

The 2017 longline bigeye tuna catch limit will apply only to U.S.-flagged longline vessels operating as part of the U.S. longline fisheries. The limit will not apply to U.S. longline vessels operating as part of the longline fisheries of American Samoa, the CNMI, or Guam. Existing regulations at 50 CFR 300.224(b), (c), and (d) detail the manner in which longline-caught bigeye tuna is attributed among the fisheries of the United States and the U.S. Participating Territories.

Consistent with the basis for the limits prescribed in CMM 2016–01 and with regulations issued by NMFS to implement bigeye tuna catch limits in U.S. longline fisheries as described below, the catch limit is measured in terms of retained catches—that is, bigeye tuna that are caught by longline gear and retained on board the vessel.

Announcement of the Limit Being Reached

As set forth under the existing regulations at 50 CFR 300.224(e), if NMFS determines that the limit is expected to be reached in 2017, NMFS will publish a notice in the **Federal Register** to announce specific fishing restrictions that will be effective from the date the limit is expected to be reached until the end of the 2017 calendar year. NMFS will publish the notice of the restrictions at least 7 calendar days before the effective date to provide vessel owners and operators with advance notice. Periodic forecasts of the date the limit is expected to be reached will be made available to the public, such as by posting on a Web site, to help vessel owners and operators plan for the possibility of the limit being reached.

Restrictions After the Limit is Reached

As set forth under the existing regulations at 50 CFR 300.224(f), if the limit is reached, the restrictions that will be in effect will include the following:

1. Retain on board, transship, or land bigeye tuna: Starting on the effective date of the restrictions and extending through December 31 of 2017, it will be prohibited to use a U.S. fishing vessel to retain on board, transship, or land bigeye tuna captured in the Convention Area by longline gear, except as follows:

First, any bigeye tuna already on board a fishing vessel upon the effective date of the restrictions can be retained on board, transshipped, and/or landed, provided that they are landed within 14 days after the restrictions become effective. A vessel that had declared to NMFS pursuant to 50 CFR 665.803(a) that the current trip type is shallow-setting is not subject to this 14-day landing restriction, so these vessels will be able to land bigeye tuna more than 14 days after the restrictions become effective.

Second, bigeye tuna captured by longline gear can be retained on board, transshipped, and/or landed if they are caught by a fishing vessel registered for use under a valid American Samoa Longline Limited Access Permit, or if they are landed in American Samoa, Guam, or the CNMI. However, the bigeye tuna must not be caught in the portion of the U.S. EEZ surrounding the Hawaiian Archipelago, and must be landed by a U.S. fishing vessel operated in compliance with a valid permit issued under 50 CFR 660.707 or 665.801.

Third, bigeye tuna captured by longline gear can be retained on board, transshipped, and/or landed if they are caught by a vessel that is included in a specified fishing agreement under 50 CFR 665.819(d), in accordance with 50 CFR 300.224(f)(iv).

2. Transshipment of bigeye tuna to certain vessels: Starting on the effective date of the restrictions and extending through December 31 of 2017, it will be prohibited to transship bigeye tuna caught in the Convention Area by longline gear to any vessel other than a U.S. fishing vessel operated in compliance with a valid permit issued under 50 CFR 660.707 or 665.801.

3. Fishing inside and outside the Convention Area: To help ensure compliance with the restrictions related to bigeye tuna caught by longline gear in the Convention Area, the interim rule establishes two additional, related prohibitions that are in effect starting on the effective date of the restrictions and extending through December 31 of 2017. First, vessels are prohibited from fishing with longline gear both inside and outside the Convention Area during the same fishing trip, with the exception of a fishing trip that is in progress at the time the announced restrictions go into effect. In that exceptional case, the vessel still must land any bigeye tuna taken in the Convention Area within 14 days of the effective date of the restrictions, as described above. Second, if a vessel is used to fish using longline gear outside the Convention Area and enters the Convention Area at any time during the same fishing trip, the longline gear on the fishing vessel must be stowed in a manner so as not to be readily available for fishing while the vessel is in the Convention Area. These two prohibitions do not apply to the following vessels: (1) Vessels on declared shallow-setting trips pursuant to 50 CFR 665.803(a); and (2) vessels operating for the purposes of this rule as part of the longline fisheries of American Samoa, Guam, or the CNMI. This second group includes vessels registered for use under valid American Samoa Longline Limited Access Permits and vessels landing their bigeye tuna catch in one of the three U.S. Participating Territories, so long as these vessels conduct fishing activities in accordance with the conditions described above, and vessels included in a specified fishing agreement under 50 CFR 665.819(d), in accordance with 50 CFR 300.224(f)(iv).

Classification

The Administrator, Pacific Islands Region, NMFS, has determined that this interim rule is consistent with the WCPFC Implementation Act and other applicable laws.

Administrative Procedure Act

There is good cause under 5 U.S.C. 553(b)(B) to waive prior notice and the opportunity for public comment on this action, because prior notice and the opportunity for public comment would be contrary to the public interest. This rule adjusts a bigeye tuna catch limit for U.S. longline fisheries in the Convention Area for 2017. Data on the amount of the 2016 overage only recently became available, and NMFS must publish the revised limit for 2017 as soon as possible to ensure it is not exceeded and the United States complies with its international legal obligations with respect to CMM 2016–01. Based on preliminary data available to date, NMFS expects that the applicable limit of 3,138 mt is likely to be reached in late summer of 2017. Delaying this rule to allow for advance notice and public comment increases the risk that more than 3,138 mt of bigeye tuna would be caught by U.S. longline fisheries operating in the WCPO, potentially constituting non-compliance by the United States with respect to the longline bigeye tuna catch limit provisions of CMM 2016–01 for calendar year 2017. Because a delay in implementing this limit for 2017 could result in the United States violating its international legal obligations to conserve tropical tuna stocks in the WCPO, allowing advance notice and the opportunity for public comment would be contrary to the public interest.

Additionally, prior notice and opportunity for public comment is unnecessary because this rule only adjusts a previously established limit for 2017 (*see* 81 FR 24772 and 81 FR 41239). In the preambles to the proposed rule and the final rule that established the 2017 limit, NMFS provided notice that if there was an overage of the limit for 2016, NMFS would adjust the 2017 limit in accordance with the provisions of CMM 2015–01 and any other pertinent Commission decisions in force at that time. (*Id.*) Moreover, affected entities have been subject to longline bigeye tuna limits in the Convention Area since 2009, and the adjusted limit is similar to the limits implemented from 2009–2016. The regulated entities have received information regarding NMFS' estimates of the 2017 longline bigeye tuna catch in the Convention Area and the approximate date the catch limit may be reached via NMFS' Web site and other means.

NMFS will, however, take and consider public comments received on this interim final and, if appropriate, NMFS will issue a revised final rule in response to public comment.

For the reasons articulated above, there is also good cause under 5 U.S.C. 553(d)(3) to waive the 30-day delay in effective date for this rule. As described above, NMFS must implement the longline bigeye tuna catch limit provisions of CMM 2016–01 for 2017 as soon as possible, in order to ensure that the catch limit is not exceeded. The catch limit is intended to reduce or otherwise control fishing pressure on bigeye tuna in the WCPO in order to restore this stock to levels capable of producing maximum sustainable yield on a continuing basis. According to the NMFS stock status determination criteria, bigeye tuna in the Pacific Ocean is currently experiencing overfishing. Failure to immediately implement the 2017 catch limit would result in additional fishing pressure on this stock, in violation of international and domestic legal obligations.

Executive Order 12866

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

Regulatory Flexibility Act

Because prior notice and opportunity for public comment are not required for this rule by 5 U.S.C. 553, or any other law, the analytical requirements of the Regulatory Flexibility Act, 5 U.S.C. 601 *et seq.,* are inapplicable. Therefore, no regulatory flexibility analysis was required and none has been prepared.

List of Subjects in 50 CFR Part 300

Administrative practice and procedure, Fish, Fisheries, Fishing, Marine resources, Reporting and recordkeeping requirements, Treaties.

Dated: August 1, 2017.

Samuel D. Rauch III,

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

For the reasons set out in the preamble, 50 CFR part 300 is amended as follows:

PART 300—INTERNATIONAL FISHERIES REGULATIONS

Subpart O—Western and Central Pacific Fisheries for Highly Migratory Species

■ 1. The authority citation for 50 CFR part 300, subpart O, continues to read as follows:

Authority: 16 U.S.C. 6901 *et seq.*

■ 2. In § 300.224, paragraph (a)(2) is revised to read as follows:

§ 300.224 Longline fishing restrictions.

(a) * * *

(2) During calendar year 2017 there is a limit of 3,138 metric tons of bigeye tuna that may be captured in the Convention Area by longline gear and retained on board by fishing vessels of the United States.

* * * * *

[FR Doc. 2017–16456 Filed 8–3–17; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 622

[Docket No. 161103999–7615–02]

RIN 0648–BG43

Fisheries of the Caribbean, Gulf of Mexico, and South Atlantic; Coastal Migratory Pelagic Resources in the Gulf of Mexico and Atlantic Region; Framework Amendment 4

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

ACTION: Final rule.

SUMMARY: NMFS issues regulations to implement management measures described in Framework Amendment 4 to the Fishery Management Plan for the Coastal Migratory Pelagics Fishery of the Gulf of Mexico and Atlantic Region (FMP) as prepared and submitted by the South Atlantic Fishery Management Council (Council). For the recreational sector, this final rule establishes bag and vessel limits, and revises the minimum size limit and accountability measures (AMs) for Atlantic migratory group cobia (Atlantic cobia). This final rule also establishes a commercial trip limit for Atlantic cobia. Framework Amendment 4 and this final rule apply to the commercial and recreational harvest of Atlantic cobia in the exclusive economic zone (EEZ) from Georgia through New York. The purpose of Framework Amendment 4 and this final rule is to slow the rate of harvest of Atlantic cobia and reduce the likelihood that landings will exceed the commercial and recreational annual catch limits (ACL), thereby triggering the AMs and reducing harvest opportunities.

DATES: This final rule is effective September 5, 2017.

ADDRESSES: Electronic copies of Framework Amendment 4 may be obtained from the Southeast Regional Office Web site at *http://sero.nmfs.noaa.gov/sustainable_fisheries/gulf_sa/cmp/2016/framework_am4/index.html.* Framework Amendment 4 includes an environmental assessment, a Regulatory Flexibility Act (RFA) analysis, and a regulatory impact review.

FOR FURTHER INFORMATION CONTACT: Karla Gore, Southeast Regional Office, NMFS, telephone: 727–551–5753, or email: *karla.gore@noaa.gov.*

SUPPLEMENTARY INFORMATION: The coastal migratory pelagic fishery of the Gulf and Atlantic Regions is managed under the FMP and includes the management of the Gulf and Atlantic migratory groups of king mackerel, Spanish mackerel, and cobia. The FMP was prepared by the Council and is implemented through regulations at 50 CFR part 622 under authority of the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act).

On February 21, 2017, NMFS published a proposed rule to implement Framework Amendment 4 and requested public comment (82 FR 11166).

The AM for the recreational sector requires that if the recreational annual catch limit (ACL) is exceeded, and the stock ACL (recreational ACL plus commercial ACL) is exceeded, the recreational AM is triggered. To determine whether an ACL was exceeded, the FMP requires that a 3-year average of landings be compared to the ACL unless an ACL changed, in which case the sequence of future ACLs begins again starting with a single year of landings compared to the ACL for that year, followed by 2-year average landings compared to the ACL in the next year, followed by a 3-year average of landings ACL for the third year and thereafter. Because Amendment 20B to the FMP changed the Atlantic cobia ACLs beginning in 2015 (80 FR 4216, January 27, 2015), NMFS could only use the 2015 landings to determine whether the recreational and stock ACLs were exceeded such that the AM was triggered for the 2016 fishing year. In 2015, recreational landings for Atlantic cobia exceeded the 2015 recreational ACL and the stock ACL, and the recreational AM required that the 2016 recreational season for Atlantic cobia in Federal waters close on June 20, 2016 (81 FR 12601, March 10, 2016).

For the 2017 fishing year, the FMP required recreational landings to be averaged for the 2015 and 2016 fishing years, and the average of those landings exceeded the 2016 recreational ACL and the 2016 stock ACL. Therefore, the recreational AM was triggered, requiring that the 2017 recreational season for Atlantic cobia in Federal waters again close early in the fishing year on January 24, 2017 (82 FR 8363, January 25, 2017).

These recreational closures likely had negative social and economic impacts on the recreational sector, including recreational anglers, charter vessels and headboat (for-hire) businesses.

The following actions in Framework Amendment 4 and this final rule are intended to slow the rate of harvest of Atlantic cobia and reduce the likelihood that sector landings will exceed the sector and stock ACLs, thereby triggering the AMs and reducing harvest opportunities. The goal is to also provide equitable access for all participants in the Atlantic cobia component of the coastal migratory pelagics fishery.

Management Measures Contained in This Final Rule

For the recreational sector, this final rule establishes bag and vessel limits, and revises the minimum size limit and AMs for Atlantic cobia. This final rule also establishes a commercial trip limit for Atlantic cobia. As a result of the recreational bag and possession limits and the commercial trip limit, Atlantic migratory cobia will no longer be subject to the two fish per person per day possession limit for limited harvest species.

Recreational Minimum Size Limit

The current minimum size limit for the recreational harvest of Atlantic cobia in the EEZ is 33 inches (83.8 cm), fork length. This final rule increases the recreational minimum size limit for the Atlantic cobia recreational sector to 36 inches (91.4 cm), fork length. This modification will result in a recreational harvest reduction in the Atlantic, that in combination with the recreational bag and vessel limits, is expected to slow the rate of recreational harvest and thereby reduce the likelihood of exceeding the recreational and stock ACLs and thereby triggering the AM.

Recreational Bag and Vessel Limits

Atlantic cobia is currently a limited harvest species with a possession limit of two cobia per person per day for both the commercial and recreational sectors. This final rule would remove Atlantic cobia from the limited harvest species possession limit and would establish a recreational bag limit of one fish per person per day or six fish per vessel, whichever is more restrictive.

Recreational AMs

This final rule would enhance the recreational AMs for Atlantic cobia. Currently, if recreational landings of Atlantic cobia exceed the recreational ACL and the sum of the commercial and recreational landings of cobia exceed the stock ACL, then during the following fishing year, the length of the recreational fishing season will be reduced to ensure that the harvest achieves the recreational ACT, but does not exceed the recreational ACL. The current recreational AM uses a moving average of the most recent 3 years of landings to compare to the recreational ACL. Finally, if Atlantic cobia are overfished, and the stock ACL is exceeded, then during the following fishing year the recreational ACL and ACT would be reduced by the amount of any recreational ACL overage.

The recreational AM in this final rule requires that if the recreational ACL and the stock ACL are exceeded, then during the following fishing year recreational landings will be monitored for a persistence in increased landings. Further, if necessary to prevent landings from exceeding the recreational ACL during the next fishing year, and based on the best scientific information available, the Assistant Administrator for Fisheries, NOAA (AA), will file a notification with the Office of the Federal Register to reduce the recreational vessel limit, to no less than two fish per vessel. NMFS notes that the recreational bag limit implemented through this final rule of one cobia per person would still apply during any reduction of the recreational vessel limit. Any reduction to the recreational vessel limit would only apply for the fishing year in which it is implemented. In addition, the AM requires that if the reduction to the vessel limit is insufficient to ensure that recreational landings will not exceed the recreational ACL, then the length of the recreational fishing season would be reduced to ensure that recreational landings do not exceed the recreational ACL in that fishing year. This AM is intended to help prevent recreational landings from exceeding the recreational ACL in that fishing year.

The recreational vessel limit and the length of the recreational fishing season would not be reduced if NMFS determines, based on the best scientific information available, that a recreational vessel limit and fishing season reduction are unnecessary to prevent landings from exceeding the recreational ACL. The Council determined that first reducing the vessel limit to no less than two fish per vessel, prior to any reduction in or closure of the recreational sector, was a preferable first step in the AM rather than first reducing the length of the recreational season, because they determined that greater negative socio-economic impacts result from a reduced season.

Also, this final rule will change the AM to compare the recreational ACL with the most recent single year of landings instead of a moving average of the most recent 3 years that was established in Amendment 18 to the FMP (76 FR 82058, December 29, 2011). The Council selected a comparison of 3-year average of landings to the recreational ACL as their preferred alternative in Amendment 18 because they decided that it would ensure that the amount of the previous year's total ACL overage would be accounted for in the subsequent year's AM protection with a reduced season, and thus would be biologically beneficial. However, the Council has reevaluated the use of a 3-year average in Framework Amendment 4, as well as in recent amendments to the FMP for the Snapper-Grouper Fishery of the South Atlantic Region (Snapper-Grouper FMP). The Council has determined that when using the methodology established through Amendment 18, an exceptionally high and unusual spike in landings incorporated into a 3-year running average could penalize anglers for the next several years whenever there is an evaluation of an ACL overage. Conversely, incorporating a year of abnormally low recreational landings into the 3-year average could result in an AM not being triggered when high landings are encountered in subsequent years, which could have negative biological effects on the stock. The revised AMs implemented here will reduce the likelihood of those longer term adverse effects.

Furthermore, the Council is taking action through Framework Amendment 4 to enhance the recreational AM by considering both a reduction in the vessel limit and the recreational season length, if needed, to prevent recreational landings from exceeding the recreational ACL in that fishing year, instead of only reducing the length of the fishing season. Thus, the revised recreational AM provides additional measures to reduce the risk of exceeding the recreational ACL while providing opportunities to extend the recreational fishing season. Using the most recent year of landings for the cobia AM is expected to result in a more timely and accurate representation of recreational landings and therefore, respond to the best scientific information available.

Commercial Trip Limit

Currently, no specific commercial trip limit applies to Atlantic cobia. However, Atlantic cobia is currently a limited harvest species subject to a possession limit of two cobia per person per day for both the commercial and recreational sectors. This final rule will remove Atlantic cobia from the limited harvest species possession limit and establish a commercial trip limit for Atlantic cobia of two fish per person per day or six fish per vessel per day, whichever is more restrictive.

Establishing a commercial trip limit with a maximum vessel limit will reduce the rate of harvest of cobia and increase the likelihood that the commercial and stock ACLs are not exceeded and the AMs are not triggered, resulting in a reduced season length or reduced vessel limit for the recreational sector and a commercial closure as a result of exceeding the commercial quota.

Comments and Responses

NMFS received a total of 133 comments on the proposed rule to implement Framework Amendment 4. The commenters included commercial, private recreational, and charter vessel fishing entities, representatives of fishing associations, and individuals from the general public. Several comments were in support of the measures in Framework Amendment 4 but some comments opposed at least one of the management measures. Most comments received were outside the scope of this amendment, including requests to modify the management boundary for Atlantic cobia, to transfer management of cobia to the states, and to reopen the Atlantic cobia recreational sector in Federal waters during 2017. Because those comments are outside of the scope of the actions considered in Framework Amendment 4 and the proposed rule, NMFS is not providing responses to those comments in this final rule. Many commenters raised the same issues, and NMFS responds to those collectively below, having identified seven distinct issues raised in the comments specific to Framework Amendment 4 and its proposed rule. These seven specific comments and NMFS' respective responses are summarized below.

Comment 1: Several commenters recommended combinations of recreational minimum size limits and harvest limits that were different than the Council's preferred alternatives. The recommendations included retaining the recreational minimum size limit at 33 inches (83.8 cm), fork length, but

decreasing the recreational bag limit to no more than one fish per person or four per vessel; increasing the minimum size limit to 36 inches (91.4 cm), total length, to reduce stress on the fish when trying to determine the fork length; increasing the minimum size limit to 40 inches (101.6 cm) but reducing recreational vessel limit to four fish per vessel; increasing the minimum size limit to 55 inches (139.7 cm) to protect spawning cobia; and creating upper and lower size limits (slot limit) to protect spawning females.

Response: The Council evaluated alternatives for recreational minimum size limits and bag and vessel limits and considered public comments before choosing their preferred alternatives. The Council selected a minimum size limit of 36 inches (91.4 cm), fork length, because it closely aligned with the minimum size limits in effect in the state waters off North Carolina and Virginia, the states that account for the majority of Atlantic cobia landings and provides increased consistency in the regulations to aid law enforcement and avoid confusion among the public. Also, a size limit greater than 36 inches (91.4 cm) would remove only larger fish, which are most likely female, and that could have an impact on cobia spawning. The Council acknowledged that the recreational sector, particularly charter vessels and headboats, would be negatively affected by vessel limits which could preclude multiple paying passengers on board unable to keep a desired fish. The Council's selection of a recreational vessel limit of six cobia per vessel per day or a reduced bag limit of one cobia per person per day, whichever is more restrictive, balances the benefits to the cobia stock with the adverse impacts to the recreational sector. Ultimately, the Council determined that a vessel limit and a minimum size limit of 36 inches (91.4 cm), fork length, best meet the objectives of the amendment and the FMP by balancing both short and long-term social and economic impacts, and are the most appropriate measures to effectively slow the rate of harvest to avoid exceeding an ACL and triggering an AM that would restrict or prohibit access.

Comment 2: The management measures proposed in Framework Amendment 4 should be re-examined after 1 year to determine if they were effective. If so, the measures should be relaxed after that time to allow an increased cobia recreational bag limit.

Response: The Council's intent and the purpose of CMP Amendment 4 is to slow the rate of harvest and extend the cobia fishing seasons. NMFS and the Council will monitor the effectiveness of the cobia regulations in achieving those goals. The Council and NMFS may change management measures in the future, as appropriate.

Comment 3: The recreational AM should apply in both Federal and state waters.

Response: The Council does not have jurisdiction in state waters and cannot require states to issue compatible regulations for cobia. The states may or may not issue regulations compatible with the Federal regulations to make fisheries management in state and Federal waters consistent, but the states are not required to do so. The Atlantic States Marine Fisheries Commission (ASMFC) is developing a fishery management plan for cobia in state waters which would complement the Council's plan for management of cobia in Federal waters, but has also recently requested that the Council consider transferring management authority of Atlantic cobia to the ASMFC. Therefore, NMFS recognizes that regulations in state and Federal waters could change as a result of future management decisions.

Comment 4: Commercial cobia fishermen should be subject to the same regulations as the recreational cobia fishermen, specifically for vessel limits, minimum size limits, and AMs.

Response: This final rule implements similar regulations for the commercial and recreational sectors, including a commercial limit of two cobia per person or six per vessel, whichever is more restrictive, and a recreational limit of one cobia per person or six per vessel, whichever is more restrictive. This rule increases the recreational minimum size limit for the Atlantic cobia recreational sector from 33 to 36 inches (91.4 cm), fork length, while the commercial minimum size limit remains at 33 inches, fork length.

In Framework Amendment 4, the Council and NMFS determined that more conservative regulations are appropriate for the recreational sector because recreational landings greatly exceeded their ACL and were 248 and 217 percent of the recreational ACL in 2015 and 2016, respectively. In comparison, commercial landings were 120 and 97 percent of the commercial ACL in 2015 and 2016, respectively, and the current sector allocations for Atlantic cobia are 8 percent of the stock ACL to the commercial sector and 92 percent to the recreational sector. There is greater uncertainty associated with catch estimates as a result of less timely catch reporting for the recreational sector compared to the commercial sector, because recreational landings are reported in 2-month intervals with a greater than 4-month time lag in the availability of information, while commercial landings are reported weekly with the information available within a week.

Therefore, the Council determined, and NMFS agrees, that different management measures between sectors for Atlantic cobia is an appropriate approach to increase the likelihood that landings do not exceed the respective sector harvest limits.

Comment 5: Recreational harvest of cobia should be allowed during the 2017 fishing season.

Response: NMFS disagrees. NMFS was required to close the 2017 recreational season as a result of the recreational AM being triggered by an ACL overage. Total landings exceeded the recreational ACL and the total ACL in 2016, which required NMFS to reduce the length of the recreational fishing season in the following fishing year (2017) based on projections of when landings will reach the ACT. NMFS reviewed the best scientific information available and determined that the entire recreational ACL for Atlantic cobia will be caught in state waters during 2017, and the stock ACL will likely be exceeded, and therefore, NMFS closed the recreational harvest of cobia on January 24 (82 FR 8363, January 25, 2017).

Comment 6: Changing the AM to use 1 year of data rather than the 3-year running average of data is flawed given the low number of cobia data intercepts. A 3-year running average of landings would more fairly represent the fishery because the data are flawed.

Response: NMFS disagrees that the data are flawed, and expects that using the most recent year of landings for the AM should result in a more timely and accurate representation of recreational landings, and better responds to the best scientific information available. The Council previously selected a 3-year running average of landings for the recreational ACL as their preferred alternative in Amendment 18 because they decided that it would be biologically beneficial for the stock by accounting for an overage in the previous year. However, the Council has reevaluated the use of a 3-year average in Framework Amendment 4, as well as in recent amendments to the Snapper-Grouper FMP. The Council has determined that with the methodology established through Amendment 18, an exceptionally high and unusual spike in landings incorporated into a 3-year running average could penalize anglers for the next several years by unnecessarily triggering AMs.

Conversely, incorporating a year of abnormally low recreational landings into the 3-year average could result in negative biological effects on the stock by not triggering an AM when it might be needed. The revised AMs implemented here will reduce the likelihood of those longer term adverse effects.

The Council is taking action in Framework Amendment 4 to enhance the recreational AM by considering both a reduction in the vessel limit and the recreational season length, if needed, to prevent recreational landings from exceeding the recreational ACL in that fishing year.

Comment 7: In violation of the Administrative Procedure Act (APA), the proposed revision to the recreational AM in Framework Amendment 4 was not subject to public comment and did not receive public support. Additionally, the public did not support the provision that allows for a shortened fishing year in the fishing year following an ACL overage.

Response: NMFS disagrees that the revisions to the recreational AM are in violation of the APA. In fact, the public had multiple opportunities to comment at various stages of the rule's development. Framework Amendment 4 was subject to and available for public comment during public hearings conducted by the Council in August 2016 and the public Council meetings during September 2016. Framework Amendment 4 was available on the Council's Web site during the amendment's development and the public was able to submit comments to the Council directly about the amendment. Additionally, the proposed rule to implement Framework Amendment 4 was subject to a 30 day public comment period, as published in the **Federal Register** (82 FR 11166, February 21, 2017).

Classification

The Regional Administrator, Southeast Region, NMFS, has determined that this final rule is consistent with Framework Amendment 4, the Magnuson-Stevens Act, and other applicable law.

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

The Magnuson-Stevens Act provides the statutory basis for this rule. No duplicative, overlapping, or conflicting Federal rules have been identified. In addition, no new reporting, recordkeeping, or other compliance requirements are introduced by this rule.

The Chief Counsel for Regulation of the Department of Commerce certified to the Chief Counsel for Advocacy of the Small Business Administration (SBA) during the proposed rule stage that this rule, if adopted, would not have significant economic impacts on a substantial number of small entities. The factual basis for this determination was published in the proposed rule and is not repeated here. NMFS did not receive any comments from SBA's Office of Advocacy or the public on the certification in the proposed rule. As a result, a final regulatory flexibility analysis is not required and none was prepared.

List of Subjects in 50 CFR Part 622

Annual catch limits, Cobia, Fisheries, Fishing, Gulf of Mexico, South Atlantic.

Dated: August 1, 2017.

Samuel D. Rauch, III,

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

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

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

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

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

■ 2. In § 622.380, revise paragraph (a) to read as follows:

§ 622.380 Size limits.

* * * * *

(a) *Cobia.* (1) In the Gulf—33 inches (83.8), fork length.

(2) *In the Mid-Atlantic or South Atlantic.* (i) 33 inches (83.8), fork length, for cobia that are sold (commercial sector).

(ii) 36 inches (91.4 cm), fork length, for cobia that are not sold (recreational sector).

* * * * *

■ 3. In § 622.382, revise paragraph (a) introductory text and add paragraph (a)(1)(vi) to read as follows:

§ 622.382 Bag and possession limits.

* * * * *

(a) *King mackerel, Spanish mackerel, and Atlantic migratory group cobia*—

(1) * * *

(vi) Atlantic migratory group cobia that are not sold (recreational sector)—1, not to exceed 6 fish per vessel per day.

* * * * *

■ 4. In § 622.383, revise paragraph (b) to read as follows:

§ 622.383 Limited harvest species.

* * * * *

(b) *Gulf migratory group cobia.* No person may possess more than two Gulf migratory group cobia per day in or from the EEZ, regardless of the number of trips or duration of a trip.

■ 5. In § 622.385, add paragraph (c) to read as follows:

§ 622.385 Commercial trip limits.

* * * * *

(c) *Cobia.* (1) *Atlantic migratory group.* Until the commercial ACL specified in § 622.384(d)(2) is reached, 2 fish per person, not to exceed 6 fish per vessel.

(2) [Reserved]

■ 6. In § 622.388, revise paragraph (f) to read as follows:

§ 622.388 Annual catch limits (ACLs), annual catch targets (ACTs), and accountability measures (AMs).

* * * * *

(f) *Atlantic migratory group cobia.* (1) The following ACLs and AMs apply to cobia that are sold (commercial sector):

(i) If the sum of the cobia landings that are sold, as estimated by the SRD, reach or are projected to reach the quota specified in § 622.384(d)(2) (ACL), the AA will file a notification with the Office of the Federal Register to prohibit the sale and purchase of cobia for the remainder of the fishing year.

(ii) In addition to the measures specified in paragraph (f)(1)(i) of this section, if the sum of the cobia landings that are sold and not sold in or from the Atlantic migratory group, as estimated by the SRD, exceeds the stock ACL, as specified in paragraph (f)(3) of this section, and Atlantic migratory group cobia are overfished, based on the most recent status of U.S. Fisheries Report to Congress, the AA will file a notification with the Office of the Federal Register, at or near the beginning of the following fishing year to reduce the applicable quota (ACL), as specified in paragraph (f)(1)(i) of this section, for that following year by the amount of any applicable sector-specific ACL overage in the prior fishing year.

(2) The following ACLs and AMs apply to cobia that are not sold (recreational sector). If recreational landings for cobia, as estimated by the SRD, exceed both the recreational ACL of 620,000 lb (281,227 kg), and the stock ACL, as specified paragraph (f)(3) of this section, then during the following fishing year, recreational landings will be monitored for a persistence in increased landings, and, if necessary, the AA will file a notification with the Office of the Federal Register to reduce the recreational vessel limit, specified in

§ 622.382(a)(1)(vi), to no less than 2 fish per vessel to ensure recreational landings achieve the recreational ACT, but do not exceed the recreational ACL in that fishing year. Any recreational vessel limit reduction that is implemented as described in this paragraph is only applicable for the fishing year in which it is implemented. Additionally, if the reduction in the recreational vessel limit is determined by the AA to be insufficient to ensure that recreational landings will not exceed the recreational ACL, the AA will also reduce the length of the recreational fishing season by the amount necessary to ensure recreational landings do not exceed the recreational ACL in that fishing year. The recreational vessel limit and the length of the recreational fishing season will not be reduced if NMFS determines, based on the best scientific information available, that a recreational vessel limit and fishing season reduction are unnecessary. The recreational ACT is 500,000 lb (226,796 kg).

(3) The stock ACL for Atlantic migratory group cobia is 670,000 lb (303,907 kg).

[FR Doc. 2017–16469 Filed 8–3–17; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 679

[Docket No. 161020985–7181–02]

RIN 0648–XF594

Fisheries of the Exclusive Economic Zone Off Alaska; Kamchatka Flounder in the Bering Sea and Aleutian Islands Management Area

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

ACTION: Temporary rule; closure.

SUMMARY: NMFS is prohibiting directed fishing for Kamchatka flounder in the Bering Sea and Aleutian Islands management area (BSAI). This action is necessary to prevent exceeding the 2017 Kamchatka flounder initial total allowable catch (ITAC) in the BSAI.

DATES: Effective 1200 hours, Alaska local time (A.l.t.), August 1, 2017, through 2400 hours, A.l.t., December 31, 2017.

FOR FURTHER INFORMATION CONTACT: Steve Whitney, 907–586–7228.

SUPPLEMENTARY INFORMATION: NMFS manages the groundfish fishery in the BSAI according to the Fishery Management Plan for Groundfish of the Bering Sea and Aleutian Islands Management Area (FMP) prepared by the North Pacific Fishery Management Council under authority of the Magnuson-Stevens Fishery Conservation and Management Act. Regulations governing fishing by U.S. vessels in accordance with the FMP appear at subpart H of 50 CFR part 600 and 50 CFR part 679.

The 2017 Kamchatka flounder ITAC in the BSAI is 4,250 metric tons (mt) as established by the final 2017 and 2018 harvest specifications for groundfish in the BSAI (82 FR 11826, February 27, 2017). In accordance with § 679.20(d)(1)(i), the Administrator, Alaska Region, NMFS (Regional Administrator), has determined that the 2017 Kamchatka flounder ITAC in the BSAI will soon be reached. Therefore, the Regional Administrator is establishing a directed fishing allowance of 2,000 mt, and is setting aside the remaining 2,250 mt as incidental catch. In accordance with § 679.20(d)(1)(iii), the Regional Administrator finds that this directed fishing allowance has been reached. Consequently, NMFS is prohibiting directed fishing for Kamchatka flounder in the BSAI.

After the effective date of this closure the maximum retainable amounts at § 679.20(e) and (f) apply at any time during a trip.

Classification

This action responds to the best available information recently obtained from the fishery. The Assistant Administrator for Fisheries, NOAA (AA), finds good cause to waive the requirement to provide prior notice and opportunity for public comment pursuant to the authority set forth at 5 U.S.C. 553(b)(B) as such requirement is impracticable and contrary to the public interest. This requirement is impracticable and contrary to the public interest as it would prevent NMFS from responding to the most recent fisheries data in a timely fashion and would delay the closure of Kamchatka flounder to directed fishing in the BSAI. NMFS was unable to publish a notice providing time for public comment because the most recent, relevant data only became available as of July 31, 2017.

The AA also finds good cause to waive the 30-day delay in the effective date of this action under 5 U.S.C. 553(d)(3). This finding is based upon the reasons provided above for waiver of prior notice and opportunity for public comment.

This action is required by § 679.20 and is exempt from review under Executive Order 12866.

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

Dated: August 1, 2017.

Emily H. Menashes,

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

[FR Doc. 2017–16449 Filed 8–1–17; 4:15 pm]

BILLING CODE 3510–22–P

Proposed Rules

Federal Register
Vol. 82, No. 149
Friday, August 4, 2017

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

Office of Energy Efficiency and Renewable Energy

10 CFR Part 430

[EERE–2017–BT–TP–0012]

Energy Conservation Program: Test Procedure for Room Air Conditioners

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

ACTION: Request for information (RFI).

SUMMARY: The U.S. Department of Energy (''DOE'') is initiating a data collection process through this request for information to consider whether to amend DOE's test procedure for room air conditioners (''room ACs''). To inform interested parties and to facilitate this process, DOE has gathered data, identifying several issues associated with the currently applicable test procedure on which DOE is interested in receiving comment. The issues outlined in this document mainly concern issues initially identified in an RFI issued in 2015 considering amendments to the current energy conservation standards and test procedure for room ACs; harmonization with the recently established portable air conditioner (''portable AC'') test procedure; clarification of the test setup and testing conditions; updated industry test procedures for room ACs; and any additional topics that may inform DOE's decisions in a future test procedure rulemaking, including methods to reduce regulatory burden while ensuring the procedure's accuracy. DOE welcomes written comments from the public on any subject within the scope of this document (including topics not raised in this RFI).

DATES: Written comments and information are requested on or before September 5, 2017.

ADDRESSES: Interested persons are encouraged to submit comments using the Federal eRulemaking Portal at *http://www.regulations.gov.* Follow the instructions for submitting comments. Alternatively, interested persons may submit comments, identified by docket number EERE–2017–BT–TP–0012, by any of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Email: RoomAC2017TP0012@ee.doe.gov.* Include the docket number EERE–2017–BT–TP–0012 in the subject line of the message.
- *Postal Mail:* Appliance and Equipment Standards Program, 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.
- *Hand Delivery/Courier:* Appliance and Equipment Standards Program, U.S. Department of Energy, Building Technologies Office, 950 L'Enfant Plaza SW., Suite 600, Washington, DC 20024. Telephone: (202) 586–6636. 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 this process, see section III of this document.

Docket: The docket for this activity, which includes **Federal Register** notices, comments, and other supporting documents/materials, is available for review at *http://www.regulations.gov.* All documents in the docket are listed in the *http://www.regulations.gov* index. However, some documents listed in the index, such as those containing information that is exempt from public disclosure, may not be publicly available.

The docket Web page can be found at *https://www.regulations.gov/docket?D=EERE-2017-BT-TP-0012.* The docket Web page will contain simple instructions on how to access all documents, including public comments, in the docket. See section III for information on how to submit comments through *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Mr. Bryan Berringer, 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) 586–0371. Email: *ApplianceStandardsQuestions@ee.doe.gov.*

Ms. Sarah Butler, U.S. Department of Energy, Office of the General Counsel, GC–33, 1000 Independence Avenue SW., Washington, DC 20585–0121. Telephone: (202) 586–1777. Email: *Sarah.Butler@hq.doe.gov.*

For further information on how to submit a comment or review other public comments and the docket, contact the Appliance and Equipment Standards Program staff at (202) 586–6636 or by email: *ApplianceStandardsQuestions@ee.doe.gov.*

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Introduction

Room ACs are included in the list of ''covered products'' for which DOE is authorized to establish and amend energy conservation standards and test procedures. (42 U.S.C. 6292(a)(2)) DOE's test procedure for room ACs appears at title 10 of the Code of Federal Regulations (''CFR'') part 430, subpart B, appendix F (''appendix F''). The following sections discuss DOE's authority to establish and amend the test procedure for room ACs, as well as relevant background information regarding DOE's consideration of test procedures for this product.

A. Authority and Background

The Energy Policy and Conservation Act of 1975 (''EPCA'' or ''the Act''),[1] Public Law 94–163 (42 U.S.C. 6291–6317, as codified), among other things, authorizes DOE to regulate the energy efficiency of a number of consumer products and industrial equipment. Title III, Part B [2] of EPCA established the Energy Conservation Program for Consumer Products Other Than Automobiles, which sets forth a variety of provisions designed to improve energy efficiency. These products include room ACs, the subject of this RFI. (42 U.S.C. 6292(a)(2))

Under EPCA, DOE's energy conservation program consists essentially of four parts: (1) Testing, (2) labeling, (3) Federal energy conservation standards, and (4) certification and enforcement procedures. Relevant provisions of the Act specifically include definitions (42 U.S.C. 6291), energy conservation standards (42 U.S.C. 6295), test procedures (42 U.S.C. 6293), labeling provisions (42 U.S.C. 6294), and the authority to require information and reports from manufacturers (42 U.S.C. 6296).

Federal energy efficiency requirements for covered products established under EPCA generally supersede State laws and regulations concerning energy conservation testing, labeling, and standards. (See 42 U.S.C. 6297) DOE may, however, grant waivers of Federal preemption for particular State laws or regulations, in accordance with the procedures and other provisions of EPCA. (42 U.S.C. 6297(d))

The Federal testing requirements consist of test procedures that manufacturers of covered products must use as the basis for: (1) Certifying to DOE that their products comply with the applicable energy conservation standards adopted pursuant to EPCA (42 U.S.C. 6295(s)), and (2) making representations about the efficiency of those consumer products (42 U.S.C. 6293(c)). Similarly, DOE must use these test procedures to determine whether the products comply with relevant standards promulgated under EPCA. (42 U.S.C. 6295(s))

Under 42 U.S.C. 6293, EPCA sets forth the criteria and procedures DOE must follow when prescribing or amending test procedures for covered products. EPCA requires that any test procedures prescribed or amended under this section shall be reasonably designed to produce test results which measure energy efficiency, energy use or estimated annual operating cost of a covered product during a representative average use cycle or period of use and shall not be unduly burdensome to conduct. (42 U.S.C. 6293(b)(3))

In addition, if DOE determines that a test procedure amendment is warranted, it must publish a proposed test procedure and offer the public an opportunity to present oral and written comments on them. (42 U.S.C. 6293(b)(2))

EPCA also requires that, at least once every 7 years, DOE evaluate test procedures for each type of covered equipment, including room ACs, to determine whether amended test procedures would more accurately or fully comply with the requirements for the test procedures to not be unduly burdensome to conduct and be reasonably designed to produce test results that reflect energy efficiency, energy use, and estimated operating costs during a representative average use cycle. (42 U.S.C. 6293(b)(1)(A)) If amended test procedures are appropriate, DOE must publish a final rule to incorporate the amendments. If DOE determines that test procedure revisions are not appropriate, DOE must publish its determination not to amend the test procedures. DOE is publishing this RFI to collect data and information to inform a potential test procedure rulemaking to satisfy the 7-year review requirement specified in EPCA, which requires that DOE publish, by January 6, 2018, either a final rule amending the test procedures or a determination that amended test procedures are not required. (42 U.S.C. 6293(b)(1)(A))

B. Rulemaking History

DOE's current test procedures for room ACs are codified at appendix F and the room AC performance metric calculations are codified at 10 CFR 430.23(f). Test procedures for room ACs were established on June 1, 1977, and were subsequently redesignated and editorially amended on June 29, 1979. 42 FR 27898 (June 1, 1977); 44 FR 37938 (June 29, 1979).

1. The January 2011 Final Rule

The Energy Independence and Security Act of 2007 (''EISA 2007'') amended EPCA, directing DOE to amend its energy efficiency test procedures for all covered products to include measures of standby mode and off mode energy consumption. (42 U.S.C. 6295(gg)(2)(A)) In compliance with the EISA 2007 requirements, on January 6, 2011, DOE published a final rule amending the room AC test procedure to include measurements of standby mode and off mode energy consumption and to introduce a new combined efficiency metric, Combined Energy Efficiency Ratio (''CEER''), that accounts for energy consumption in active mode, standby mode, and off mode. 76 FR 972. DOE also incorporated a new standard, International Electrotechnical Commission (''IEC'') Standard 62301, to measure the standby and off mode energy consumption. Id. In addition to IEC Standard 62301, the final rule updated the references to standards developed by the American National Standards Institute (''ANSI''), the Association of Home Appliance Manufacturers (''AHAM''), and the American Society of Heating, Refrigerating, and Air-Conditioning Engineers (''ASHRAE''). Id. In sum, the current room AC test procedure incorporates by reference three industry test standards: (1) ANSI/AHAM RAC–1–2008, ''Room Air Conditioners'' (''ANSI/AHAM RAC–1''); [3] (2) ANSI/ASHRAE Standard 16–1983 (RA 2009), ''Method of Testing for Rating Room Air Conditioners and Packaged Terminal Air Conditioners'' (''ANSI/ASHRAE 16''); [4] and (3) IEC Standard 62301, ''Household electrical appliances—Measurement of standby power (first edition June 2005)''.[5]

2. The June 2015 Request for Information

DOE published an RFI (hereinafter the ''June 2015 RFI'') regarding the energy conservation standards and the test procedures for room ACs. 80 FR 34843 (June 18, 2015). In addition to soliciting information regarding the energy conservations standards, the June 2015 RFI discussed and sought comment on the following test procedure related items: (1) Potential updates to the energy efficiency metric that would address performance in additional operating modes; (2) alternate methods for measuring cooling mode performance; (3) addressing heating mode performance and any relevant test methods, existing industry standards, operating conditions, and associated test burden; (4) methods for measuring part-load performance and the prevalence of units on the market with components optimized for efficient part-load operation; (5) testing and certification of units that can operate on multiple voltages; and (6) the energy usage

[1] All references to EPCA in this document refer to the statute as amended through the Energy Efficiency Improvement Act of 2015 (EEIA 2015), Public Law 114–11 (April 30, 2015).

[2] For editorial reasons, upon codification in the U.S. Code, Part B was redesignated Part A.

[3] Copies can be purchased from *http://webstore.ansi.org.*

[4] Copies can be purchased from *http://www.techstreet.com.*

[5] Copies can be purchased from *http://webstore.iec.ch.*

associated with connected functionality. 80 FR 34843, 34846 34848. DOE received comments from interested parties pertaining to the test procedure in response to the June 2015 RFI.[6]

II. Request for Information and Comments

In the following sections, DOE has identified a variety of issues on which it seeks input to aid in the development of the technical and economic analyses regarding whether amended test procedures for room ACs may be warranted. Specifically, DOE is requesting comment on any opportunities to streamline and simplify testing requirements for room ACs.

Additionally, DOE welcomes comments on other issues relevant to the conduct of this process that may not specifically be identified in this document. In particular, DOE notes that under Executive Order 13771, ''Reducing Regulation and Controlling Regulatory Costs,'' Executive Branch agencies such as DOE are directed to manage the costs associated with the imposition of expenditures required to comply with Federal regulations. See 82 FR 9339 (Feb. 3, 2017). Pursuant to that Executive Order, DOE encourages the public to provide input on measures DOE could take to lower the cost of its regulations applicable to room ACs consistent with the requirements of EPCA. DOE also requests comment on the benefits and burdens of adopting any industry/voluntary consensus-based or other appropriate test procedure, without modification.

A. Harmonization With the Portable Air Conditioners Test Procedure

As discussed in the June 2015 RFI, DOE believes that consumers regard portable ACs and room ACs as similar products with similar function and consumer utility, because both are self-encased products powered by single-phase electric current that utilize refrigerant to provide cooling to defined spaces, and their product usage is broadly similar. See 80 FR 34843, 34845. Consequently, DOE believes that consumers are inclined to compare the two products based on their rated capacity and efficiency. Thus, harmonizing the test conditions for room ACs and portable ACs may allow consumers to make a more accurate comparison of the energy use or efficiency of the two products.

DOE published a test procedure final rule for portable ACs on June 1, 2016 (hereinafter the ''June 2016 Portable AC Final Rule''), in which DOE established test procedures for portable ACs in 10 CFR part 430, subpart B, appendix CC (''appendix CC''). 81 FR 35242. DOE assessed both the new portable AC test procedure and the room AC test procedure to determine whether any significant differences would impede an accurate consumer comparison of measured performance of the two covered products. DOE notes that the portable AC test procedure differentiates between single-duct and dual-duct portable ACs, which require different test conditions. For the purposes of the comparison with room ACs, DOE specifically considered the dual-duct testing provisions in the portable AC test procedure, because dual-duct portable ACs are most similar to room ACs in that the condenser inlet air is drawn from the unconditioned space, unlike single-duct portable ACs that draw condenser inlet air from the conditioned space. DOE identified several key differences between the test procedures in appendix F and appendix CC that lead to incomparable results. Specifically, the portable AC test procedure includes (1) two sets of test conditions for dual-duct portable ACs, one at 95 degrees Fahrenheit (''°F'') dry-bulb and 75 °F wet-bulb outdoor temperature (identical to the room AC test procedure) and the other at 83 °F dry-bulb and 67.5 °F wet-bulb outdoor temperature; [7] (2) a requirement that the test unit be set up and tested with all manufacturer-provided materials and the associated heat losses be accounted for in the energy efficiency metric; and (3) the consideration of energy consumption in off-cycle mode (as defined in appendix CC). In light of these differences, DOE is requesting feedback in this RFI on whether amendments to the room AC test procedure are warranted to harmonize the two test procedures in order to enable a more accurate comparison of portable AC and room AC performance. In the following subsections, DOE describes the differences between the two test procedures in greater detail and requests information on key topics related to their harmonization.

1. Test Conditions

In a portable AC test procedure supplemental notice of proposed rulemaking (''SNOPR''), published on November 27, 2015 (hereinafter the ''November 2015 Portable AC SNOPR''), DOE developed a climate analysis to determine the ideal cooling mode test conditions for portable ACs. 80 FR 74020, 74026. DOE considered 2012 climate data from the National Centers for Environmental Information (''NCEI'') [8] of the National Oceanic and Atmospheric Administration (''NOAA'') to determine the average dry-bulb temperature and relative humidity associated with the hottest 750 hours of the year in each state for which data were available.[9] DOE then reviewed room AC ownership data from the 2009 Residential Energy Consumption Survey (''RECS'') [10] to identify room AC ownership by geographic region, as a proxy for portable AC ownership.[11] Based on these data, DOE used a weighted-average approach to combine the average temperature and humidity for each state to determine a national average test condition representative of the hottest 750 hours of the year. DOE found that the national average dry-bulb temperature and relative humidity associated with the hottest 750 hours are 83 °F and 45 percent, respectively. DOE then proposed two cooling mode test conditions for dual-duct portable ACs in the November 2015 Portable AC SNOPR: (1) A higher outdoor temperature condition based on AHAM PAC–1–2015, ''Portable Air Conditioners'' (95 °F dry-bulb and 75 °F wet-bulb temperature), representing high-temperature conditions when cooling is most needed; and (2) the lower outdoor temperature condition based on the weighted-average temperature and humidity observed during the hottest 750 hours (83 °F dry-bulb and 67.5 °F wet-bulb temperature). Id. In the June 2016 Portable AC Final Rule, DOE adopted in appendix CC the cooling mode test conditions proposed in the November 2015 Portable AC SNOPR. 81 FR 35242, 35249–35251.

In the June 2016 Portable AC Final Rule, DOE also established an energy efficiency metric, CEER, which provides a representative measure of overall

[6] All public comments are located in the energy conservation standards docket: *http://www.regulations.gov/#!docketDetail;D=EERE-2014-BT-STD-0059.*

[7] For single-duct portable ACs, testing is only required at the 95 °F dry-bulb and 75 °F wet-bulb outdoor test condition. Single-duct portable ACs do not intake air from the unconditioned space and therefore performance of the unit while testing would be unchanged by the adjustment in outdoor test conditions. Thus, DOE requires numerical adjustments for the 83 °F dry-bulb and 67.5 °F wet-bulb outdoor condition when determining the seasonally adjusted cooling capacity and CEER for single-duct portable ACs. This approach minimizes test burden yet ensures that the performance of a single-duct and dual-duct portable AC can be compared.

[8] The NCEI was formerly known as the National Climate Data Center.

[9] NCEI climate data are available online at: *https://www.ncdc.noaa.gov/crn/qcdatasets.html.*

[10] RECS data are available online at: *http://www.eia.gov/consumption/residential/data/2009/.*

[11] DOE utilized RECS data for room ACs because such data were not available for portable ACs.

portable AC performance that accounts for the variability in performance during the cooling season. CEER for dual-duct portable ACs is calculated as follows:

$$CEER = \left[\frac{ACC_{95}}{\left(\frac{AEC_{95} + AEC_T}{k \times t}\right)}\right] \times 0.2 + \left[\frac{ACC_{83}}{\left(\frac{AEC_{83} + AEC_T}{k \times t}\right)}\right] \times 0.8$$

Where:

ACC_{95} = adjusted cooling capacity measured at an outdoor temperature of 95 °F in British thermal units per hour (Btu/h);

ACC_{83} = adjusted cooling capacity measured at an outdoor temperature of 83 °F in Btu/h;

AEC_{95} = total annual energy consumption in cooling mode at an outdoor temperature of 95 °F in kilowatt-hours per hear (kWh/year);

AEC_{83} = total annual energy consumption in cooling mode at an outdoor temperature of 83 °F in kWh/year;

k = 0.001 kWh/Wh conversion factor for watt-hours to kilowatt-hours;

t = number of hours per year, 8,760.

81 FR 35242, 35268.

Room ACs are currently tested with a single outdoor test condition, 95 °F dry-bulb and 75 °F wet-bulb temperature, which aligns with only one of the two cooling mode test conditions for dual-duct portable ACs. Considering the similarities between the two products (*i.e.,* consumer utility, internal components, *etc.*) and the potential for consumers to compare the energy use or efficiency of both products, DOE seeks comment on whether it would be appropriate to harmonize the two test procedures by including an additional test condition for room AC cooling mode testing (83 °F dry-bulb and 67.5 °F wet-bulb temperature). Should this harmonization of test conditions occur, DOE would also investigate the applicability of the portable AC energy metric and determine if any modifications would be necessary for its application to room ACs.

As noted in the June 2015 RFI, the current room AC test procedure measures only the full-load performance at outdoor ambient conditions of 95 °F dry-bulb and 75 °F wet-bulb temperature. 80 FR 34843, 34848. Therefore, available technologies that improve part-load performance, such as variable-speed compressors and variable-opening expansion devices, are not considered in the determination of the rated performance of a room AC under the current test procedure. Id. DOE expects that harmonizing the room AC test procedure with the portable AC test procedure by including an additional cooling mode test condition potentially would ensure the room AC efficiency metric is more representative of actual use, and it will capture benefits associated with variable-speed compressors and other components that improve part-load performance.

Issue A.1.1 DOE seeks feedback on the harmonization of the room AC test procedure with the DOE test procedure for dual-duct portable ACs, specifically related to the inclusion of an additional cooling mode test condition.

Issue A.1.2 DOE seeks information on the test burden and other potential impacts associated with the inclusion of an additional cooling mode test condition in the room AC test procedure.

Issue A.1.3 DOE seeks information on the merits and limitations of utilizing the CEER efficiency metric adopted for dual-duct portable ACs for the purposes of rating room ACs.

Issue A.1.4 DOE seeks information on the implementation and operation of variable-speed compressors and other components that will improve part-load performance for room ACs, and whether the dual rating conditions specified for testing of dual-duct portable ACs would capture benefits of these technologies for room ACs and be included in the revised test procedure.

2. Installation Heat Transfer and Leakage

The portable AC test procedure in appendix CC requires that the test unit be set up and tested with all manufacturer-provided materials (including the ducts, connectors for attaching the duct(s) to the test unit, sealing, insulation, and window mounting fixtures) to ensure that the performance measured during the test is reflective of actual installation and operation. The portable AC test procedure also accounts for the impacts of infiltration air, which is caused by negative pressure in the conditioned space created by the unit's operation, thereby driving unconditioned air into the space and impacting the overall cooling provided by the unit to the conditioned space.

Room ACs are typically installed with side curtains or other window or wall mounting installation materials that, during typical operation, may allow air to leak through or around the materials and would impact the cooling provided to the conditioned space. However, DOE notes that when conducting the calorimeter test prescribed in ANSI/ASHRAE Standard 16 (as referenced by the current DOE room AC test procedure), the test unit is set up so all air leakage around the unit that would normally be present in a typical installation is precluded by means of sealing.

Considering the requirements of EPCA for DOE to adopt test procedures that are representative of an average use cycle, which would encompass typical installation and operation, DOE requests comment on testing in accordance with the manufacturer-provided installation materials.

Issue A.2.1 DOE seeks feedback on the harmonization of the room AC test set up requirements with those in the portable AC test procedure, specifically related to installation with all manufacturer-provided installation materials.

Issue A.2.2 DOE requests information and data related to air and heat leakage through and around room AC installation materials, specifically side curtains and wall sleeves, which the current room AC test procedure does not capture. DOE request comment on whether these losses should be considered given the requirements of EPCA.

3. Off-Cycle Mode

In the June 2016 Portable AC Final Rule, DOE adopted a definition for ''off-cycle mode'' as a mode in which the portable air conditioner: (1) Has cycled off its main cooling or heating function by thermostat or temperature sensor signal; (2) may or may not operate its fan or blower; and (3) will reactivate the main function according to the thermostat or temperature sensor signal. 81 FR 35242, 35265. DOE notes that this off-cycle mode definition for portable ACs is different from an off-cycle mode definition that DOE proposed on December 9, 2008, in a NOPR for the previous room AC test procedure rulemaking, which explicitly excluded fan operation from the off-cycle mode.[12]

[12] DOE notes that the definition for off-cycle mode proposed in the December 2008 NOPR was not adopted in the June 2011 Final Rule.

73 FR 74639, 74645 (Dec. 9, 2008) (hereinafter the ''December 2008 NOPR''). By excluding the periods of fan operation from off-cycle mode that would be expected for a typical installation and usage, the definition proposed in the December 2008 NOPR excluded potentially significant energy consumption when compared to the definition adopted for portable ACs.

DOE also established provisions for determining the average off-cycle mode power in the June 2016 Portable AC Final Rule. 81 FR 35242, 35267. The portable AC off-cycle mode test is conducted following the cooling mode test under the same ambient conditions, and includes a 5-minute delay prior to measuring power consumption to allow for a brief period of fan operation while the evaporator returns to its non-cooling state. Because the evaporator is still cool at the end of compressor operation following cooling mode, additional room cooling is possible through continued fan operation at relatively low energy consumption. Therefore, DOE included the 5-minute delay before the start of off-cycle mode testing to prevent penalizing manufacturers for utilizing the cooling potential of the evaporator following the compressor cycle.

In the June 2015 RFI, DOE requested comment on the merits and/or limitations of accounting for energy modes not currently included in the room AC test procedure, including off-cycle mode, referencing the definition proposed in the December 2008 NOPR. 80 FR 34843, 34846. In response to the June 2015 RFI, DOE received a comment opposed to the inclusion of off-cycle mode in the DOE test procedure for room ACs. However, due to the significant difference between that definition and the definition of off-cycle mode established in the portable AC test procedure, DOE is requesting feedback on including provisions for measuring average off-cycle mode power in the room AC test procedure, consistent with the portable AC test procedure.

Issue A.3.1 DOE seeks feedback on the harmonization of the room AC test procedure with the portable AC test procedure, specifically related to the inclusion of off-cycle mode in the room AC test procedure.

Issue A.3.2 DOE seeks feedback on the applicability of the portable AC off-cycle mode definition, provisions to measure average off-cycle mode power, and the inclusion of off-cycle mode in the efficiency metric for room ACs.

Issue A.3.3 DOE requests information and data related to off-cycle mode, including input power levels, fan operation, time spent in that mode, *etc.*

B. Test Setup and Air Sampling

The current DOE room AC test procedure references certain sections of ANSI/AHAM RAC–1 and ANSI/ASHRAE 16 for the room AC cooling mode test conditions and test methods. Section 4.2.7 of ANSI/ASHRAE 16 requires the calorimeter chamber conditions to be verified by air sampled from a location that is representative of the temperatures surrounding the unit and that simulate the conditions in which the unit operates in the field. DOE notes that there is no procedure to verify if the measured chamber temperature reading is representative of conditions at the test unit condenser and evaporator inlet, which may be affected by recirculation from the condenser and evaporator exhaust, respectively, thereby potentially reducing test repeatability and reproducibility. As a result, DOE is seeking comment on this issue and any potential modifications to the test procedure that should be considered as part of this investigative effort.

Issue B.1 DOE welcomes information on more specific requirements for air sampling device positioning within the calorimeter chamber to improve test repeatability.

C. Room Air Conditioner Referenced Test Procedures

1. American National Standards Institute/Association of Home Appliance Manufacturers RAC–1

The cooling mode test in appendix F is conducted in accordance with the testing conditions, methods, and calculations in sections 4, 5, 6.1, and 6.5 of the 2008 version of ANSI/AHAM RAC–1. Since DOE last revised its room AC test procedure in 2011, ANSI/AHAM RAC–1 has been updated and the current standard was released in 2015 (ANSI/AHAM RAC–1–2015, ''Room Air Conditioners''). Based on review of the 2015 standard, DOE believes that the updates to ANSI/AHAM RAC–1 provide added specificity, but do not substantively impact the results of DOE's cooling mode test. Accordingly, DOE does not expect that updating the references to ANSI/AHAM RAC–1 in the room AC test procedure at appendix F would substantively affect testing results. DOE further notes that the 2015 update to ANSI/AHAM RAC–1 included adjustments to section organization, and DOE would consider updating section references as necessary if the 2015 version of ANSI/AHAM RAC–1 is incorporated by reference in the room AC test procedure at appendix F.

Issue C.1.1 DOE seeks feedback on whether the references to ANSI/AHAM RAC–1–2008 in its test procedure at appendix F should be updated to certain sections of the most current version of ANSI/AHAM RAC–1, ANSI/AHAM RAC–1–2015.

2. American National Standards Institute/American Society of Heating, Refrigerating, and Air-Conditioning Engineers Standard 16

Appendix F currently references in its provisions for cooling mode test conditions, methods, and calculations the 1983 version of ANSI/ASHRAE 16, which was reaffirmed in 2009. ANSI/AHAM RAC–1–2015 also references the 1983 version of ANSI/ASHRAE 16 reaffirmed in 2009. A new version of ANSI/ASHRAE 16 was published in 2016, which includes many significant updates to the standard, including heating mode testing and an air enthalpy test approach as an alternative to the calorimeter approach, while the general cooling mode methodology remains unchanged.

Issue C.2.1 DOE seeks feedback on the applicability of the recent updates to ANSI/ASHRAE 16 to the room AC test procedure in appendix F.

Issue C.2.2 DOE welcomes feedback on whether the test procedure in appendix F should continue to reference the version of ANSI/ASHRAE 16 that was reaffirmed in 2009, consistent with the referenced version in both ANSI/AHAM RAC–1–2008 and ANSI/AHAM RAC–1–2015, or if appendix F should reference the 2016 version of ANSI/ASHRAE 16. If appendix F were to reference the 2016 version of ANSI/ASHRAE 16, DOE seeks information on modified instructions that would be required in appendix F to continue to reference certain sections of ANSI/AHAM RAC–1.

D. Other Test Procedure Topics

In addition to the issues identified earlier in this document, DOE welcomes comment on any other aspect of the existing test procedure for room ACs not already addressed by the specific areas identified in this document. DOE particularly seeks information that would improve the repeatability, reproducibility, and consumer representativeness of the test procedure. DOE also requests information that would help DOE create a procedure that would limit manufacturer test burden through streamlining or simplifying testing requirements. Comments regarding the repeatability and reproducibility are also welcome.

DOE also requests feedback on any potential amendments to the existing

test procedure that could be considered to address impacts on manufacturers, including small businesses. Regarding the Federal test method, DOE seeks comment on the degree to which the DOE test procedure should consider and be harmonized with the most recent relevant industry standards for room ACs and whether there are any changes to the Federal test method that would provide additional benefits to the public.

Additionally, DOE requests comment on whether the existing test procedure limits a manufacturer's ability to provide additional features to consumers on room ACs. DOE particularly seeks information on how the test procedure could be amended to reduce the cost of new or additional features and make it more likely that such features are included on room ACs.

III. Submission of Comments

DOE invites all interested parties to submit in writing by September 5, 2017, comments and information on matters addressed in this RFI and on other matters relevant to DOE's test procedure for room ACs. These comments and information will aid in the development of a test procedure NOPR for room ACs if DOE determines that amended test procedures may be appropriate for these products.

Submitting comments via *http://www.regulations.gov.* The *http://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 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. 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 *http://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 *http://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.

DOE processes submissions made through *http://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 *http://www.regulations.gov* provides after you have successfully uploaded your comment.

Submitting comments via email, hand delivery, or mail. Comments and documents submitted via email, hand delivery, or mail also will be posted to *http://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 on 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, please provide all items on a CD, if feasible. It is not necessary to submit printed copies. No facsimiles (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, written in English and 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. According to 10 CFR 1004.11, any person submitting information that he or she believes to be confidential and exempt by law from public disclosure should submit via email, postal mail, or hand delivery two well-marked copies: one copy of the document marked confidential including all the information believed to be confidential, and one copy of the document marked ''non-confidential'' with the information believed to be confidential deleted. Submit these documents via email or on a CD, if feasible. DOE will make its own determination about the confidential status of the information and treat it according to its determination.

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 which 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).

DOE considers public participation to be a very important part of the process for developing test procedures. DOE actively encourages the participation and interaction of the public during the comment period in each stage of the rulemaking process. Interactions with and between members of the public provide a balanced discussion of the issues and assist DOE in the rulemaking process. Anyone who wishes to be added to the DOE mailing list to receive future notices and information about this process or would like to request a public meeting should contact Appliance and Equipment Standards Program staff at (202) 586–6636 or via email at *ApplianceStandardsQuestions@ee.doe.gov.*

Issued in Washington, DC, on July 27, 2017.

Kathleen Hogan, Ph.D.,

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

[FR Doc. 2017–16441 Filed 8–3–17; 8:45 am]

BILLING CODE –P

Notices

Federal Register
Vol. 82, No. 149
Friday, August 4, 2017

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

DEPARTMENT OF AGRICULTURE

Forest Service

Fresno and Madera Counties Resource Advisory Committee

AGENCY: Forest Service, USDA.

ACTION: Notice of meeting.

SUMMARY: The Fresno and Madera Counties Resource Advisory Committee (RAC) will meet in Clovis, 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 the Act.

DATES: The meeting will be held on August 31, 2017, from 6:00 p.m. to 8:00 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 Sierra National Forest (NF) Supervisor's Office, 1600 Tollhouse Road, Clovis, 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 the Sierra NF Supervisor's Office. Please call ahead to facilitate entry into the building.

FOR FURTHER INFORMATION CONTACT: Julie Roberts, RAC Coordinator, by phone at 559–297–0706 or via email at *jaroberts@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. Discuss and agree on general operating procedures,
2. Elect a chair,
3. Review project proposals, and
4. Possibly vote to recommend project proposals for Title II Funds.

The meeting is open to the public. The agenda will include time for people to make oral statements of three minutes or less. Individuals wishing to make an oral statement should request in writing by August 18, 2017, to be scheduled on the agenda. Anyone who would like to bring related matters to the attention of the committee may file written statements with the committee staff before or after the meeting. Written comments and requests for time for oral comments must be sent to Julie Roberts, RAC Coordinator, Sierra NF Supervisor's Office, 1600 Tollhouse Road, Clovis, California 93611; by email to *jaroberts@fs.fed,* or via facsimile to 559–294–4809.

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 10, 2017.

Glenn Casamassa,

Associate Deputy Chief, National Forest System.

[FR Doc. 2017–16427 Filed 8–3–17; 8:45 am]

BILLING CODE 3411–15–P

DEPARTMENT OF AGRICULTURE

Forest Service

Fresno and Madera Counties Resource Advisory Committee

AGENCY: Forest Service, USDA.

ACTION: Notice of meeting.

SUMMARY: The Fresno and Madera Counties Resource Advisory Committee (RAC) will meet in Clovis, 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 the Act.

DATES: The meeting will be held on August 24, 2017, from 6:00 p.m. to 8:00 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 Sierra National Forest (NF) Supervisor's Office, 1600 Tollhouse Road, Clovis, 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 the Sierra NF Supervisor's Office. Please call ahead to facilitate entry into the building.

FOR FURTHER INFORMATION CONTACT: Julie Roberts, RAC Coordinator, by phone at 559–297–0706 or via email at *jaroberts@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. Discuss and agree on general operating procedures,
2. Elect a chair,
3. Review project proposals, and
4. Possibly vote to recommend project proposals for Title II Funds.

The meeting is open to the public. The agenda will include time for people to make oral statements of three minutes or less. Individuals wishing to make an oral statement should request in writing by August 11, 2017, to be scheduled on the agenda. Anyone who would like to bring related matters to the attention of the committee may file written statements with the committee staff

before or after the meeting. Written comments and requests for time for oral comments must be sent to Julie Roberts, RAC Coordinator, Sierra NF Supervisor's Office, 1600 Tollhouse Road, Clovis, California 93611; by email to *jaroberts@fs.fed,* or via facsimile to 559–294–4809.

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 10, 2017.

Glenn Casamassa,

Associate Deputy Chief, National Forest System.

[FR Doc. 2017–16428 Filed 8–3–17; 8:45 am]

BILLING CODE 3411–15–P

DEPARTMENT OF COMMERCE

International Trade Administration

Request for Applicants for Appointment to the United States-Brazil CEO Forum

AGENCY: International Trade Administration, Department of Commerce.

ACTION: Notice.

SUMMARY: In March 2007, the Governments of the United States and Brazil established the U.S.-Brazil CEO Forum. This notice announces the opportunity for up to twelve individuals for appointment to the U.S. Section of the Forum. The three-year term of the incoming members of the U.S. Section starts on October 1, 2017, and will expire September 30, 2020. Nominations received in response to this notice will also be considered for on-going appointments to fill any future vacancies that may arise before September 30, 2020.

DATES: Applications for immediate consideration should be received no later than close of business August 25, 2017. After that date, applications will continue to be accepted through September 30, 2020 to fill any new vacancies that may arise.

ADDRESSES: Please send requests for consideration to Raquel Silva, Office of Latin America and the Caribbean, U.S. Department of Commerce, either by email at *Raquel.Silva@trade.gov* or by mail to U.S. Department of Commerce, 1401 Constitution Avenue NW., Room 30014, Washington, DC 20230.

FOR FURTHER INFORMATION CONTACT: Raquel Silva, Office of Latin America and the Caribbean, U.S. Department of Commerce, telephone: (202) 482–4157.

SUPPLEMENTARY INFORMATION: The Secretary of Commerce and the Director of the National Economic Council, together with the Planalto Casa Civil Minister (Presidential Chief of Staff) and the Brazilian Minister of Industry, Foreign Trade & Services, co-chair the U.S.-Brazil CEO Forum (Forum), pursuant to the Terms of Reference signed in March 2007 by the U.S. and Brazilian governments, as amended, which set forth the objectives and structure of the Forum. The Terms of Reference may be viewed at: *http://www.trade.gov/ceo-forum/.* The Forum, consisting of both private and public sector members, brings together leaders of the respective business communities of the United States and Brazil to discuss issues of mutual interest, particularly ways to strengthen the economic and commercial ties between the two countries. The Forum consists of the U.S. and Brazilian Government co-chairs and a Committee comprised of private sector members. The Committee is composed of two Sections, each consisting of approximately ten to twelve members from the private sector, representing the views and interests of the private sector business community in the United States and Brazil. Each government appoints the members to its respective Section. The Committee provides joint recommendations to the two governments that reflect private sector views, needs and concerns regarding the creation of an economic environment in which their respective private sectors can partner, thrive and enhance bilateral commercial ties to expand trade between the United States and Brazil.

This notice seeks candidates to fill up to twelve positions on the U.S. Section of the Forum as well as any future vacancies that may arise before September 30, 2020. Each candidate must be the Chief Executive Officer or President (or have a comparable level of responsibility) of a U.S.-owned or -controlled company that is incorporated in and has its main headquarters in the United States and that is currently doing business in both Brazil and the United States. Each candidate also must be a U.S. citizen or otherwise legally authorized to work in the United States and able to travel to Brazil and locations in the United States to attend official Forum meetings as well as independent U.S. Section and Committee meetings. In addition, the candidate may not be a registered foreign agent under the Foreign Agents Registration Act of 1938, as amended. Evaluation of applications for membership in the U.S. Section by eligible individuals will be based on the following criteria:

—A demonstrated commitment by the individual's company to the Brazilian market either through exports or investment.

—A demonstrated strong interest in Brazil and its economic development.

—The ability to offer a broad perspective and business experience to the discussions.

—The ability to address cross-cutting issues that affect the entire business community.

—The ability to initiate and be responsible for activities in which the Forum will be active.

Members will be selected on the basis of who will best carry out the objectives of the Forum as stated in the Terms of Reference establishing the U.S.-Brazil CEO Forum. The U.S. Section of the Forum should also include members that represent a diversity of business sectors and geographic locations. To the extent possible, U.S. Section members also should represent a cross-section of small, medium, and large firms.

U.S. members will receive no compensation for their participation in Forum-related activities. Individual members will be responsible for all travel and related expenses associated with their participation in the Forum, including attendance at Committee and Section meetings. Only appointed members may participate in official Forum meetings; substitutes and alternates will not be designated. According to the current Terms of Reference, members are normally to serve three-year terms, but may be reappointed.

To be considered for membership, please submit the following information as instructed in the **ADDRESSES** and **DATES** captions above: Name(s) and title(s) of the individual(s) requesting consideration; name and address of company's headquarters; location of incorporation; information that the company is U.S.-owned or U.S.-controlled; size of the company; size of company's export trade, investment, and nature of operations or interest in Brazil; an affirmative statement that the applicant meets all Forum eligibility criteria and is neither registered nor required to register as a foreign agent under the Foreign Agents Registration Act of 1938, as amended; and a brief

statement of why the candidate should be considered, including information about the candidate's ability to initiate and be responsible for activities in which the Forum will be active. Applications will be considered as they are received. All candidates will be notified of whether they have been selected.

Dated: July 31, 2017.

Alexander Peacher,

Acting Director for the Office of Latin America & the Caribbean.

[FR Doc. 2017–16455 Filed 8–3–17; 8:45 am]

BILLING CODE 3510–HE–P

DEPARTMENT OF COMMERCE

International Trade Administration

Corporation for Travel Promotion (dba Brand USA)

AGENCY: International Trade Administration, U.S. Department of Commerce.

ACTION: Notice of an opportunity for travel and tourism industry leaders to apply for membership on the Board of Directors of the Corporation for Travel Promotion.

SUMMARY: The Department of Commerce is currently seeking applications from travel and tourism leaders from specific industries for membership on the Board of Directors (Board) of the Corporation for Travel Promotion (dba Brand USA). The purpose of the Board is to guide the Corporation for Travel Promotion on matters relating to the promotion of the United States as a travel destination and communication of travel facilitation issues, among other tasks.

DATES: All applications must be received by the National Travel and Tourism Office by close of business on September 29, 2017.

ADDRESSES: Electronic applications may be sent to: *CTPBoard@trade.gov.* Written applications can be submitted to Isabel Hill, Director, National Travel and Tourism Office, U.S. Department of Commerce, Mail Stop 10007, 1401 Constitution Avenue NW., Washington, DC 20230. Telephone: 202.482.0140. Email: *Isabel.Hill@trade.gov.*

FOR FURTHER INFORMATION CONTACT: Julie Heizer, Deputy Director, National Travel and Tourism Office, Mail Stop 10003, 1401 Constitution Avenue NW., Washington, DC, 20230. Telephone: 202.482.4904. Email: *julie.heizer@trade.gov.*

SUPPLEMENTARY INFORMATION:

Background: The Travel Promotion Act of 2009 (TPA) was signed into law on March 4, 2010, and was amended in July 2010 and December 2014. The TPA established the Corporation for Travel Promotion (the Corporation), as a non-profit corporation charged with the development and execution of a plan to (A) provide useful information to those interested in traveling to the United States; (B) identify and address perceptions regarding U.S. entry policies; (C) maximize economic and diplomatic benefits of travel to the United States through the use of various promotional tools; (D) ensure that international travel benefits all States and the District of Columbia, and (E) identify opportunities to promote tourism to rural and urban areas equally, including areas not traditionally visited by international travelers.

The Corporation (doing business as Brand USA) is governed by a Board of Directors, consisting of 11 members with knowledge of international travel promotion or marketing, broadly representing various regions of the United States. The TPA directs the Secretary of Commerce (after consultation with the Secretary of Homeland Security and the Secretary of State) to appoint the Board of Directors for the Corporation.

At this time, the Department will be selecting three individuals with the appropriate expertise and experience from specific sectors of the travel and tourism industry to serve on the Board as follows:

(A) 1 shall have appropriate expertise and experience in small business/retail;

(B) 1 shall have appropriate expertise and experience in state tourism office; and

(C) 1 shall have appropriate expertise and experience in travel distribution services.

To be eligible for Board membership, individuals must have international travel and tourism marketing experience, be a current or former chief executive officer, chief financial officer, or chief marketing officer or have held an equivalent management position. Additional consideration will be given to individuals who have experience working in U.S. multinational entities with marketing budgets, and/or who are audit committee financial experts as defined by the Securities and Exchange Commission (in accordance with section 407 of Pub. L. 107–204 [15 U.S.C. 7265]). Individuals must be U.S. citizens, and in addition, cannot be federally registered lobbyists or registered as a foreign agent under the Foreign Agents Registration Act of 1938, as amended.

Those selected for the Board must be able to meet the time and effort commitments of the Board.

Board members serve at the discretion of the Secretary of Commerce (who may remove any member of the Board for good cause). The terms of office of each member of the Board appointed by the Secretary shall be three (3) years. Board members can serve a maximum of two consecutive full three-year terms. Board members are not considered Federal government employees by virtue of their service as a member of the Board and will receive no compensation from the Federal government for their participation in Board activities. Members participating in Board meetings and events may be paid actual travel expenses and per diem when away from their usual places of residence by the Corporation.

Individuals who want to be considered for appointment to the Board should submit:

1. Name, title, and personal resume of the individual requesting consideration, including address, email address and phone number; and

2. A brief statement of why the person should be considered for appointment to the Board. This statement should also address the individual's relevant international travel and tourism marketing experience and indicate clearly the sector or sectors enumerated above in which the individual has the requisite expertise and experience. Individuals who have the requisite expertise and experience in more than one sector can be appointed for only one of those sectors. Appointments of members to the Board will be made by the Secretary of Commerce.

3. An affirmative statement that the applicant is a U.S. citizen and further, is not required to register as a foreign agent under the Foreign Agents Registration Act of 1938, as amended, is also required.

Dated: August 1, 2017.

Julie P. Heizer,

Deputy Director, National Travel and Tourism Office.

[FR Doc. 2017–16486 Filed 8–3–17; 8:45 am]

BILLING CODE 3510–DR–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

Meeting of the Advisory Committee on Commercial Remote Sensing

ACTION: Notice of meeting.

SUMMARY: The Advisory Committee on Commercial Remote Sensing (''ACCRES'' or ''the Committee'') will meet August 24, 2017.

DATES: The meeting is scheduled as follows: August 24, 2017, 9:00 a.m.–4:30 p.m. There will be a one hour lunch break from 11:45 a.m.–12:45 p.m.

ADDRESSES: The meeting will be held at the George Washington University, The Elliot School of International Affairs—Lindner Commons, 1957 E Street NW., Washington, DC 20052.

FOR FURTHER INFORMATION CONTACT: Samira Patel, NOAA/NESDIS/CRSRA, 1335 East West Highway, Room 8247, Silver Spring, Maryland 20910; (301) 713–7077 or *samira.patel@noaa.gov.*

SUPPLEMENTARY INFORMATION: As required by Section 10(a)(2) of the Federal Advisory Committee Act, 5 U.S.C. App. 2 (FACA) and its implementing regulations, *see* 41 CFR 102–3.150, notice is hereby given of the meeting of ACCRES. ACCRES was established by the Secretary of Commerce (Secretary) on May 21, 2002, to advise the Secretary of Commerce through the Under Secretary of Commerce for Oceans and Atmosphere on matters relating to the U.S. commercial remote sensing space industry and on the National Oceanic and Atmospheric Administration's activities to carry out the responsibilities of the Department of Commerce set forth in the National and Commercial Space Programs Act of 2010 (51 U.S.C. 60101 *et seq.*).

Purpose of the Meeting and Matters To Be Considered

The meeting will be open to the public pursuant to Section 10(a)(1) of the FACA. During the meeting, the Committee will receive updates on NOAA's Commercial Remote Sensing Regulatory Affairs activities, discuss updates to the new licensing conditions, and report out on committee task groups. The Committee will also discuss the new draft legislation related to commercial remote sensing activities recently introduced in the U.S. House of Representatives. The Committee will be available to receive public comments on its activities.

Special Accommodations

The meeting is physically accessible to people with disabilities. Requests for special accommodations may be directed to Samira Patel, NOAA/NESDIS/CRSRA, 1335 East West Highway, Room 8247, Silver Spring, Maryland 20910; (301) 713–7077 or *samira.patel@noaa.gov.*

Additional Information and Public Comments

Any member of the public who plans to attend the open meeting should RSVP to Samira Patel at (301) 713–7077, or *samira.patel@noaa.gov* by August 18, 2017. Any member of the public wishing further information concerning the meeting or who wishes to submit oral or written comments should contact Tahara Dawkins, Designated Federal Officer for ACCRES, NOAA/NESDIS/CRSRA, 1335 East West Highway, Room 8260, Silver Spring, Maryland 20910; (301) 713–3385 or *tahara.dawkins@noaa.gov.* Copies of the draft meeting agenda can be obtained from Samira Patel at (301) 713–7077, or *samira.patel@noaa.gov.*

ACCRES expects that public statements presented at its meetings will not be repetitive of previously-submitted oral or written statements. In general, each individual or group making an oral presentation may be limited to a total time of five minutes. Written comments sent to NOAA/NESDIS/CRSRA on or before August 18, 2017 will be provided to Committee members in advance of the meeting. Comments received too close to the meeting date will normally be provided to Committee members at the meeting.

Stephen M. Volz,

Assistant Administrator for Satellite and Information Services.

[FR Doc. 2017–16470 Filed 8–3–17; 8:45 am]

BILLING CODE 3510–HR–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XF590

Taking and Importing Marine Mammals; Taking Marine Mammals Incidental to U.S. Navy Marine Structure Maintenance and Pile Replacement in Washington

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

ACTION: Notice; receipt of application for Letters of Authorization; request for comments and information.

SUMMARY: NMFS has received a request from the U.S. Navy (Navy) for authorization to take small numbers of marine mammals incidental to conducting construction activities related to marine structure maintenance and pile replacement at facilities in Washington, over the course of five years from the date of issuance. Pursuant to regulations implementing the Marine Mammal Protection Act (MMPA), NMFS is announcing receipt of the Navy's request for the development and implementation of regulations governing the incidental taking of marine mammals. NMFS invites the public to provide information, suggestions, and comments on the Navy's application and request.

DATES: Comments and information must be received no later than September 5, 2017.

ADDRESSES: Comments on the applications should be addressed to Jolie Harrison, Chief, Permits and Conservation Division, Office of Protected Resources, National Marine Fisheries Service. Physical comments should be sent to 1315 East-West Highway, Silver Spring, MD 20910 and electronic comments should be sent to *ITP.Laws@noaa.gov.*

Instructions: NMFS is not responsible for comments sent by any other method, to any other address or individual, or received after the end of the comment period. Comments received electronically, including all attachments, must not exceed a 25-megabyte file size. Attachments to electronic comments will be accepted in Microsoft Word or Excel or Adobe PDF file formats only. All comments received are a part of the public record and will generally be posted to the Internet at *www.nmfs.noaa.gov/pr/permits/incidental/research.htm* without change. All personal identifying information (*e.g.,* name, address) voluntarily submitted by the commenter may be publicly accessible. Do not submit confidential business information or otherwise sensitive or protected information.

FOR FURTHER INFORMATION CONTACT: Ben Laws, Office of Protected Resources, NMFS, (301) 427–8401. An electronic copy of the Navy's application may be obtained online at: *www.nmfs.noaa.gov/pr/permits/incidental/construction.htm.* In case of problems accessing these documents, please call the contact listed above.

SUPPLEMENTARY INFORMATION:

Background

Sections 101(a)(5)(A) and (D) of the MMPA (16 U.S.C. 1361 *et seq.*) direct the Secretary of Commerce (as delegated to NMFS) to allow, upon request, the incidental, but not intentional, taking of small numbers of marine mammals by U.S. citizens who engage in a specified activity (other than commercial fishing) within a specified geographical region if certain findings are made and either

regulations are issued or, if the taking is limited to harassment, a notice of a proposed authorization is provided to the public for review.

An authorization for incidental takings shall be granted if NMFS finds that the taking will have a negligible impact on the species or stock(s), will not have an unmitigable adverse impact on the availability of the species or stock(s) for subsistence uses (where relevant), and if the permissible methods of taking and requirements pertaining to the mitigation, monitoring and reporting of such takings are set forth.

NMFS has defined ''negligible impact'' in 50 CFR 216.103 as an impact resulting from the specified activity that cannot be reasonably expected to, and is not reasonably likely to, adversely affect the species or stock through effects on annual rates of recruitment or survival.

The MMPA states that the term ''take'' means to harass, hunt, capture, kill or attempt to harass, hunt, capture, or kill any marine mammal.

Except with respect to certain activities not pertinent here, the MMPA defines ''harassment'' as: Any act of pursuit, torment, or annoyance which (i) has the potential to injure a marine mammal or marine mammal stock in the wild (Level A harassment); or (ii) has the potential to disturb a marine mammal or marine mammal stock in the wild by causing disruption of behavioral patterns, including, but not limited to, migration, breathing, nursing, breeding, feeding, or sheltering (Level B harassment).

Summary of Request

On July 24, 2017, NMFS received an adequate and complete application from the Navy requesting authorization for take of marine mammals incidental to construction activities related to marine structure maintenance and pile replacement at five Naval installations in Washington inland waters. The requested regulations would be valid for five years, from 2018 through 2023. The Navy plans to conduct necessary work, including impact and vibratory pile driving, to repair and maintain existing marine structures at six installations. The proposed action may incidentally expose marine mammals occurring in the vicinity to elevated levels of underwater sound, thereby resulting in incidental take, primarily by Level B harassment but also including some expected potential for Level A harassment. Therefore, the Navy requests authorization to incidentally take marine mammals.

Specified Activities

Washington Naval installations covered by this request include Naval Base Kitsap Bangor, Naval Base Kitsap Bremerton, Naval Base Kitsap Keyport, Naval Base Kitsap Manchester, Zelatched Point, and Naval Station Everett. To ensure continuance of necessary missions at these installations, the Navy must conduct annual maintenance and repair activities at existing marine waterfront structures, including removal and replacement of piles of various types and sizes. Exact timing and amount of necessary in-water work is unknown, but the Navy estimates replacing up to 822 structurally unsound piles over the 5-year period, including individual actions currently planned and estimates for future marine structure repairs. Construction will include use of impact and vibratory pile driving, including removal and installation of steel, concrete, plastic, and timber piles.

Information Solicited

Interested persons may submit information, suggestions, and comments concerning the Navy's request (see **ADDRESSES**). NMFS will consider all information, suggestions, and comments related to the request during the development of proposed regulations governing the incidental taking of marine mammals by the Navy, if appropriate.

Dated: August 1, 2017.

Catherine Marzin,

Acting Deputy Director, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 2017–16454 Filed 8–3–17; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XF541

Takes of Marine Mammals Incidental to Specified Activities; Taking Marine Mammals Incidental to a Pier Replacement Project in San Diego, CA

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

ACTION: Notice; proposed incidental harassment authorization; request for comments.

SUMMARY: NMFS has received a request from the U.S. Navy (Navy) for authorization to take marine mammals incidental to construction and demolition activities as part of a pier replacement project. Pursuant to the Marine Mammal Protection Act (MMPA), NMFS is requesting comments on its proposal to issue an incidental harassment authorization (IHA) to the Navy to incidentally take marine mammals, by Level B Harassment only, during the specified activity. NMFS will consider public comments prior to making any final decision on the issuance of the requested MMPA authorizations and agency responses will be summarized in the final notice of our decision.

DATES: Comments and information must be received no later than September 5, 2017.

ADDRESSES: Comments on the application should be addressed to Jolie Harrison, Chief, Permits and Conservation Division, Office of Protected Resources, National Marine Fisheries Service. Physical comments should be sent to 1315 East-West Highway, Silver Spring, MD 20910 and electronic comments should be sent to *ITP.McCue@noaa.gov.*

Instructions: NMFS is not responsible for comments sent by any other method, to any other address or individual, or received after the end of the comment period. Comments received electronically, including all attachments, must not exceed a 25-megabyte file size. Attachments to electronic comments will be accepted in Microsoft Word or Excel or Adobe PDF file formats only. All comments received are a part of the public record and will generally be posted to the Internet at *www.nmfs.noaa.gov/pr/permits/incidental/construction.htm* without change. All personal identifying information (*e.g.,* name, address) voluntarily submitted by the commenter may be publicly accessible. Do not submit confidential business information or otherwise sensitive or protected information.

FOR FURTHER INFORMATION CONTACT: Laura McCue, Office of Protected Resources, NMFS, (301) 427–8401. Electronic copies of the application and supporting documents, as well as a list of the references cited in this document, may be obtained online at: *www.nmfs.noaa.gov/pr/permits/incidental/construction.htm.* In case of problems accessing these documents, please call the contact listed above.

SUPPLEMENTARY INFORMATION:

Background

Sections 101(a)(5)(A) and (D) of the MMPA (16 U.S.C. 1361 *et seq.*) direct the Secretary of Commerce (as delegated to NMFS) to allow, upon request, the

incidental, but not intentional, taking of small numbers of marine mammals by U.S. citizens who engage in a specified activity (other than commercial fishing) within a specified geographical region if certain findings are made and either regulations are issued or, if the taking is limited to harassment, a notice of a proposed authorization is provided to the public for review.

An authorization for incidental takings shall be granted if NMFS finds that the taking will have a negligible impact on the species or stock(s), will not have an unmitigable adverse impact on the availability of the species or stock(s) for subsistence uses (where relevant), and if the permissible methods of taking and requirements pertaining to the mitigation, monitoring and reporting of such takings are set forth.

NMFS has defined ''negligible impact'' in 50 CFR 216.103 as an impact resulting from the specified activity that cannot be reasonably expected to, and is not reasonably likely to, adversely affect the species or stock through effects on annual rates of recruitment or survival.

The MMPA states that the term ''take'' means to harass, hunt, capture, kill or attempt to harass, hunt, capture, or kill any marine mammal.

Except with respect to certain activities not pertinent here, the MMPA defines ''harassment'' as: Any act of pursuit, torment, or annoyance which (i) has the potential to injure a marine mammal or marine mammal stock in the wild (Level A harassment); or (ii) has the potential to disturb a marine mammal or marine mammal stock in the wild by causing disruption of behavioral patterns, including, but not limited to, migration, breathing, nursing, breeding, feeding, or sheltering (Level B harassment).

National Environmental Policy Act (NEPA)

To comply with the National Environmental Policy Act of 1969 (NEPA; 42 U.S.C. 4321 *et seq.*) and NOAA Administrative Order (NAO) 216–6A, NMFS must review our proposed action (*i.e.,* the issuance of an incidental harassment authorization) with respect to potential impacts on the human environment.

This action is consistent with categories of activities identified in CE B4 of the Companion Manual for NOAA Administrative Order 216–6A, which do not individually or cumulatively have the potential for significant impacts on the quality of the human environment and for which we have not identified any extraordinary circumstances that would preclude this categorical exclusion. Accordingly, NMFS has preliminarily determined that the issuance of the proposed IHA qualifies to be categorically excluded from further NEPA review.

We will review all comments submitted in response to this notice prior to concluding our NEPA process or making a final decision on the IHA request.

Summary of Request

On June 19, 2017, we received a request from the Navy for an IHA to take marine mammals incidental to pile installation and demolition associated with a pier replacement project in San Diego Bay at Naval Base Point Loma in San Diego, CA (NBPL), including a separate monitoring plan. The Navy also submitted a draft monitoring report on June 13, 2017, pursuant to requirements of the previous IHA. These final application and monitoring plan were deemed adequate and complete on July 20, 2017. The pier replacement project is planned to occur over multiple years; this proposed IHA would cover only the fifth year of work and would be valid for a period of one year from the date of issuance. Hereafter, use of the generic term ''pile driving'' may refer to both pile installation and removal unless otherwise noted. The Navy's request is for take of nine species of marine mammals by Level B harassment. Neither the Navy nor NMFS expect mortality to result from this activity and, therefore, an IHA is appropriate.

Monitoring reports are available online at *www.nmfs.noaa.gov/pr/permits/incidental/construction.htm* and provide environmental information related to proposed issuance of this IHA for public review and comment.

This proposed IHA would cover one year of a larger project for which the Navy obtained prior IHAs and this request for take authorization is for the fifth year of the project, following the IHAs issued effective from October 8, 2016, through October 7, 2017 (81 FR 66628), September 1, 2013, through August 31, 2014 (78 FR 44539), from October 8, 2014, through October 7, 2015 (79 FR 65378), and from October 8, 2015, through October 7, 2016 (80 FR 62032). The Navy complied with all the requirements (*e.g.,* mitigation, monitoring, and reporting) of the previous IHA. Monitoring reports are available online at *www.nmfs.noaa.gov/pr/permits/incidental/construction.htm* and provide environmental information related to proposed issuance of this IHA for public review and comment.

Description of the Specified Activity

Overview

NBPL provides berthing and support services for Navy submarines and other fleet assets. The existing fuel pier serves as a fuel depot for loading and unloading tankers and Navy underway replenishment vessels that refuel ships at sea (''oilers''), as well as transferring fuel to local replenishment vessels and other small craft operating in San Diego Bay, and is the only active Navy fueling facility in southern California. Portions of the pier are over one hundred years old, while the newer segment was constructed in 1942. The pier as a whole is significantly past its design service life and does not meet current construction standards.

The Navy plans to demolish and remove the existing pier and associated pipelines and appurtenances while simultaneously replacing it with a generally similar structure that meets relevant standards for seismic strength and is designed to better accommodate modern Navy ships. Demolition and construction are planned to occur in two phases to maintain the fueling capabilities of the existing pier while the new pier is being constructed. During the fifth year of construction (the specified activity considered under this proposed IHA), the Navy anticipates construction at two locations: The fuel pier area and at the Naval Mine and Anti-Submarine Warfare Command (NMAWC), where the Navy's Marine Mammal Program (MMP) was temporarily moved during fuel pier construction (see Figure 1–1 in the Navy's application). At the fuel pier, the Navy anticipates finishing all the demolition, including removal of 180 square precast (PC) concrete and poly-concrete piles of varying sizes up to 24-in using a hydraulic pile cutter; cutting 30 66-in and 5 84-in concrete-filled steel caissons with a diamond wire saw; and removing 12 30-in steel piles by cutting with a plasma torch. Only the hydraulic pile cutting and diamond saw cutting of caissons reach Level B acoustic thresholds.

At the NMAWC, twenty-three 16-in diameter PC concrete guide piles would be driven (by vibratory and/or impact hammer) to restore gangway access to the recreational marina. Sixty-four 16-in diameter round PC concrete guide piles will be removed at NMAWC by jetting followed by dry-pulling; dry pulling does not reach the Level B acoustic thresholds. Table 1 summarizes the construction activities during the fifth year of the Navy's project.

TABLE 1—CONSTRUCTION PROPOSED TO BE COMPLETE DURING FIFTH YEAR OF NBPL PROJECT

Location and pile type or structure	Number
Removal/Demolition	
Pier 180 (Fuel Pier):	
Poly-concrete and PC concrete piles up to 24-in square	180
66″ concrete filled steel caissons	30
84″ concrete filled steel caissons	5
30″ steel at temporary south dolphin	12
Total—Pier 180 (Fuel Pier)	227
NMAWC:	
Extract 16″ PC round concrete	64
Total—NMAWC	64
Total Piles Removed	291
Installation	
NMAWC:	
16″ PC concrete guide piles	23
Total Piles Removed	23

Notes: PC = precast.

The proposed actions with the potential to incidentally harass marine mammals within the waters adjacent to NBPL are vibratory and impact pile installation and certain demolition (*i.e.,* pile removal) techniques. Concurrent use of multiple pile driving rigs is not planned.

Dates and Duration

The proposed activities that would be authorized by this IHA, during the fifth year of work associated with the fuel pier project, would occur for one year from the date of issuance of this proposed IHA. Under the terms of a memorandum of understanding (MOU) between the Navy and the U.S. Fish and Wildlife Service (FWS), all noise- and turbidity-producing in-water activities in designated least tern foraging habitat are to be avoided during the period when least terns are present and engaged in nesting and foraging (a window from approximately May 1 through September 15). However, it is possible that in-water work not expected to result in production of significant noise or turbidity (*e.g.,* demolition activities) could occur at any time during the period of validity of this proposed IHA. The conduct of any such work would be subject to approval from FWS under the terms of the MOU. We expect that in-water construction work would primarily occur from October through April. Pile driving would occur during normal working hours (approximately 7 a.m. to 6 p.m.), and would not occur earlier than 45 minutes after sunrise or later than 45 minutes before sunset.

Specific Geographic Region

NBPL is located on the peninsula of Point Loma near the mouth and along the northern edge of San Diego Bay (see Figures 1–1 and 1–2 in the Navy's application). San Diego Bay is a narrow, crescent-shaped natural embayment oriented northwest-southeast with an approximate length of 24 kilometers (km) and a total area of roughly 4,500 hectares (ha). The width of the bay ranges from 0.3 to 5.8 km, and depths range from 23 meters (m) mean lower low water (MLLW) near the tip of Ballast Point to less than 2 m at the southern end (see Figure 2–1 of the Navy's application). San Diego Bay is a heavily urbanized area with a mix of industrial, military, and recreational uses. The northern and central portions of the bay have been shaped by historic dredging to support large ship navigation. Dredging occurs as necessary to maintain constant depth within the navigation channel. Outside the navigation channel, the bay floor consists of platforms at depths that vary slightly. Sediments in northern San Diego Bay are relatively sandy as tidal currents tend to keep the finer silt and clay fractions in suspension, except in harbors and elsewhere in the lee of structures where water movement is diminished. Much of the shoreline consists of riprap and manmade structures. San Diego Bay is heavily used by commercial, recreational, and military vessels, with an average of over 80,000 vessel movements (in or out of the bay) per year (not including recreational boating within the Bay) (see Table 2–2 of the Navy's application). For more information about the specific geographic region, please see section 2.3 of the Navy's application.

Detailed Description of Activities

In order to provide context, we described the entire project in our **Federal Register** notice of proposed authorization associated with the first-year IHA (78 FR 30873; May 23, 2013). Please see that document for an overview of the entire fuel pier replacement project, or see the Navy's Environmental Assessment (2013) for more detail. Here, we provide an overview of relevant construction methods before describing only the specific project portions scheduled for completion during the fifth work window. Please see Section 1 of the Navy's application for full detail of construction scheduling for this period. For the fifth year of work, approximately 23 concrete piles would be installed at NMAWC. The Navy does not anticipate needing future IHAs related to completion of construction at NBPL, but would apply for a sixth IHA if construction is not completed under this IHA.

Methods, Pile Installation—Vibratory hammers, which can be used to either install or extract a pile, contain a system of counter-rotating eccentric weights powered by hydraulic motors and are designed in such a way that horizontal vibrations cancel out, while vertical vibrations are transmitted into the pile. The pile driving machine is lifted and positioned over the pile by means of an excavator or crane, and is fastened to the pile by a clamp and/or bolts. The vibrations produced cause liquefaction

of the substrate surrounding the pile, enabling the pile to be extracted or driven into the ground using the weight of the pile plus the hammer. Impact hammers use a rising and falling piston to repeatedly strike a pile and drive it into the ground.

Non-steel piles are typically impact-driven for their entire embedment depth, in part because non-steel piles are often displacement piles (as opposed to pipe piles) and require some impact to allow substrate penetration. However, jetting may be used to advance displacement piles to a certain embedment depth. Pile jetting utilizes a directed flow of pressurized water to assist in pile placement. The jetting technique liquefies the soils at the pile tip during pile placement, reducing the friction between adjacent sub-grade soil particles around the water jet. This greatly decreases the bearing capacity of the soils below the pile tip, causing the pile to descend toward its final tip elevation with much less soil resistance, largely under its own weight.

Methods, Pile Removal—There are multiple methods for pile removal. During previous demolition, piles were generally removed by cutting at the mudline, which can be accomplished in various ways. Piles are expected to be removed during this fifth-year IHA primarily using a pile cutter, which is a bladed hydraulic device that shears the pile off. The preferred method of removing the caisson elements is to cut them at the mudline and then into two sections using a diamond wire cutting saw. Existing caisson elements would be removed with a clamshell, which is a dredging bucket consisting of two similar halves that open/close at the bottom and are hinged at the top. The clamshell would be used to grasp and lift large components.

Piles may also be removed by simply dry pulling, or pulling after the pile has been loosened using a vibratory hammer or a pneumatic chipper. Jetting may be another option to loosen piles that could not be removed through the previous procedures. Pile removal is not generally expected to require the use of vibratory extraction or pneumatic chipping, and these methods are considered as contingency in the event other methods of extraction are not successful.

Construction—Construction work during the proposed fifth year of activity would include driving of concrete piles to restore dock access at NMAWC following Navy Marine Mammal Program (MMP) removal from NMAWC. This work is expected to require a total of 25 days.

Demolition—Demolition of the old pier will be completed now that the new pier is operational. Much of the demolition work will be above-water, involving removal of the pier, pilings, plastic camels and fenders, but in-water structure removal will also occur, as described above under *Methods, Pile Removal.* The in-water portion of demolition work planned during the period of this proposed IHA is expected to require 156 days in total.

NMAWC—As described above, the Navy also plans to return the MMP to its permanent location near the fuel pier, requiring extraction and installation of concrete piles to return the NMAWC site to its original condition. This work is expected to require 15 days.

Description of Work Accomplished

During the first in-water work season (2013–14), two primary activities were conducted: Relocation of the MMP and the Indicator Pile Program (IPP). During the second in-water work season (2014–15), the IPP was concluded and simultaneous construction of the new pier and demolition of the old pier begun. Production pile driving continued during the third in-water work season (2015–16). During the fourth in-water work season (2016–17) pile driving of fender piles and structural piles for the mooring dolphins for the new fuel pier was conducted, including two IPP piles, demolition of the old fuel pier, and pile driving and extraction at NMAWC.

The Navy MMP, administered by Space and Naval Warfare Systems (SPAWAR) Command Systems Center (SSC), was moved approximately three kilometers to the NMAWC (see Figures 1–1 and 1–2 of the Navy's Year 1 monitoring report). Although not subject to the MMPA, SSC's working animals were temporarily relocated so that they will not be affected by the project. Over the course of 25 in-water construction days from January 28 to March 13, 2014, the Navy removed thirty and installed 81 concrete piles (12- and 16-in). See Table 3–2 of the Navy's Year 1 monitoring report for details. Installation was accomplished via a D19–42 American Pile Driving Equipment, Inc. (APE) diesel hammer with energy capacity of 23,566–42,800 ft-lbs and fitted with a hydraulic tripping cylinder with four adjustable power settings that could be reset while driving. Pile removal was accomplished by jetting and dead pull.

The IPP was designed to validate the length of pile required and the method of installation (vibratory and impact) as well as to validate acoustic sound pressure levels of the various sizes and locations (*i.e.,* shallow versus deeper water) of installed piles. Nine steel pipe test piles were vibratory- and impact-driven over ten work days from April 28 to May 15, 2014, including two 30-in and seven 36-in piles. All piles were initially installed using an APE Variable Moment 250 VM Vibratory Hammer Extractor powered by a model 765 hydraulic power source creating a maximum driving force of 2,389 kilonewtons (269 tons). Impact pile driving equipment consisted of a single acting diesel impact hammer model D62–22 DELMAG with energy capacity of 76,899–153,799 ft-lbs and fitted with a hydraulic tripping cylinder with four adjustable power settings that could be reset while driving. One additional 36-in pile was installed in Spring 2015, under the Year 2 IHA, to conclude the IPP.

Production pile driving associated with construction of the new pier was begun in Fall 2014 and continued into Spring 2015. Both vibratory and impact driving was used, as described above, to install 238 steel pipe piles (four 18-in, 31 30-in, and 203 36-in diameter). Hammers used were the same as those described above. Demolition activity began in Spring 2015, and included the removal of four caissons, eighteen concrete fender piles, and a portion of concrete decking from the existing fuel pier. In total, this work consisted of 100 days of activity from October 16, 2014, through April 29, 2015. Of these 100 days of in-water work, 18 days involved only impact driving, 15 days included only vibratory driving, and 65 days where both types of driving occurred. The remaining two days involved only demolition activities. Please see the Year 2 monitoring report for more information.

Production pile driving continued in early 2016 during three distinct construction periods from January 11 through April 30, 2016, with 161 piles installed over the course of 50 days. Because most structural steel pipe piles were installed under the Year 2 IHA, this work primarily involved placement of non-structural concrete fender piles. Both vibratory and impact driving was used, as described above, to install 132 16-in polycarbonate coated concrete fender piles and 23 24 x 30-in concrete fender piles. In addition, six 30-in steel pipe piles were installed as structural elements to support a mooring dolphin. Hammers used for the steel piles were the same as those described above. The 16-in concrete piles were driven using an APE single action diesel impact hammer model D25–32, with energy capacity of 29,484–58,245 ft-lbs and

fitted with a manual power level modulator and shut off trip. The 24 x 30-in concrete piles were driven using an APE single action diesel impact hammer model D80–42, with energy capacity of 127,008–198,450 ft-lbs and fitted with a manual power level modulator and shut off trip. No demolition occurred during this period. Of the 50 days of in-water work, 45 days involved only impact driving, two days included only vibratory driving, and three days where both types of driving occurred. Please see the Year 3 monitoring report for more information.

Production pile driving during Year 4 construction, from October 8, 2016 to April 30, 2017, included 68 piles of three types of piles driven with two different methods over 34 days: 30-in steel piles were driven with both vibratory and impact hammers, and the 24 x 30-in concrete and 16-in poly-concrete piles were installed with impact hammers. High pressure water jetting were used to ''pre-drill'' holes for the 24 x 30 in piles. In addition, Structural piles were installed for two dolphins to the south of the new fuel pier, fender piles were installed on the east and west sides of the new fuel pier as well as on one of the dolphins, and a single 16-inch poly-concrete pile (concrete pile lined with a polycarbonate outer sheath) was driven on the west side of the pier.

Demolition during Year 4 included removal of the caissons from the north side of the old fuel pier, as well as removal of structural and fender piles sizes under, and adjacent to, the south and north sections of the old pier. Eighteen 84-in caissons were cut using a wire saw. A total of 278 piles were clipped, including 14-in, 18-in, and 24-in fender piles and 13-in polycarbonate and poly-concrete piles. Of the 69 days of in-water work, 42 days involved pile clipping and 27 days involved pile cutting. Please see the Year 4 monitoring report for more information.

Additional work may be conducted under the existing IHA between September 15 and October 7, 2017, in which case the submitted monitoring report would be amended as necessary.

Proposed mitigation, monitoring, and reporting measures are described in detail later in this document (please see *Proposed Mitigation* and *Proposed Monitoring and Reporting*).

Description of Marine Mammals in the Area of the Specified Activity

Species with the expected potential to be present during all or a portion of the in-water work window include the California sea lion (*Zalophus californianus*), harbor seal (*Phoca vitulina richardii*), northern elephant seal (*Mirounga angustirostris*), gray whale (*Eschrichtius robustus*), bottlenose dolphin (*Tursiops truncatus truncatus*), Pacific white-sided dolphin (*Lagenorhynchus obliquidens*), Risso's dolphin (*Grampus griseus*), and either short-beaked or long-beaked common dolphins (*Delphinus* spp.). California sea lions are present year-round and are very common in the project area, while bottlenose dolphins and harbor seals are common and likely to be present year-round but with more variable occurrence in San Diego Bay. Gray whales may be observed in San Diego Bay sporadically during migration periods. The remaining species are known to occur in nearshore waters outside San Diego Bay, but are generally only rarely observed near or in the bay. However, recent observations indicate that these species may occur in the project area and therefore could potentially be subject to incidental harassment from the aforementioned activities.

There are four marine mammal species which are either resident or have known seasonal occurrence in the vicinity of San Diego Bay, including the California sea lion, harbor seal, bottlenose dolphin, and gray whale (see Figures 3–1 through 3–4 and 4–1 in the Navy's application). In addition, common dolphins (see Figure 3–4 in the Navy's application), the Pacific white-sided dolphin, Risso's dolphin, and northern elephant seals are known to occur in deeper waters in the vicinity of San Diego Bay and/or have been observed within the bay during the course of this project's monitoring. Although the latter three species of cetacean would not generally be expected to occur within the project area, the potential for changes in occurrence patterns in conjunction with recent observations leads us to believe that authorization of incidental take is warranted. Common dolphins have been documented regularly at the Navy's nearby Silver Strand Training Complex, and were observed in the project area during previous years of project activity. The Pacific white-sided dolphin has been sighted along a previously used transect on the opposite side of the Point Loma peninsula (Merkel and Associates, 2008) and there were several observations of Pacific white-sided dolphins during Year 2 monitoring. Risso's dolphin is fairly common in southern California coastal waters (*e.g.,* Campbell *et al.,* 2010), and could occur in the bay. Northern elephant seals are included based on their continuing increase in numbers along the Pacific coast (Carretta *et al.,* 2016) and the likelihood that animals that reproduce on the islands offshore of Baja California and mainland Mexico—where the population is also increasing—could move through the project area during migration, as well as the observation of a juvenile seal near the fuel pier in April 2015.

Note that common dolphins could be either short-beaked (*Delphinus delphis delphis*) or long-beaked (*D. delphis bairdii*) subspecies. While it is likely that common dolphins observed in the project area would be long-beaked, as it is the most frequently stranded species in the area from San Diego Bay to the U.S.-Mexico border (Danil and St. Leger 2011), the species distributions overlap and it is unlikely that observers would be able to differentiate them in the field. Therefore, we consider that any common dolphins observed—and any incidental take of common dolphins—could be either long- or short-beaked common dolphins.

In addition, other species that occur in the Southern California Bight may have the potential for isolated occurrence within San Diego Bay or just offshore. In particular, a short-finned pilot whale (*Globicephala macrorhynchus*) was observed off Ballast Point, and a Steller sea lion (*Eumetopias jubatus monteriensis*) was seen in the project area during Year 2. These species are not typically observed near the project area and, unlike the previously mentioned species, we do not believe it likely that they will occur in the future. Given the unlikelihood of their exposure to sound generated from the project, these species are not considered further.

Sections 3 and 4 of the application summarize available information regarding status and trends, distribution and habitat preferences, and behavior and life history, of the potentially affected species. Additional information regarding population trends and threats may be found in NMFS's Stock Assessment Reports (SAR; *www.nmfs.noaa.gov/pr/sars/*) and more general information about these species (*e.g.,* physical and behavioral descriptions) may be found on NMFS's Web site (*www.nmfs.noaa.gov/pr/species/mammals/*).

Table 2 lists all marine mammal species with expected potential for occurrence in the vicinity of NBPL during the project timeframe and summarizes key information, including regulatory status under the MMPA and ESA and potential biological removal (PBR), where known. See also Figures 3–1 through 3–5 of the Navy's application for observed occurrence of

marine mammals in the project area. For taxonomy, we follow Committee on Taxonomy (2016). PBR is defined by the MMPA as the maximum number of animals, not including natural mortalities, that may be removed from a marine mammal stock while allowing that stock to reach or maintain its optimum sustainable population (as described in NMFS's SARs). While no mortality is anticipated or authorized here, PBR and annual serious injury and mortality from anthropogenic sources are included here as gross indicators of the status of the species and other threats.

Marine mammal abundance estimates presented in this document represent the total number of individuals that make up a given stock or the total number estimated within a particular study or survey area. NMFS's stock abundance estimates for most species represent the total estimate of individuals within the geographic area, if known, that comprises that stock. For some species, this geographic area may extend beyond U.S. waters. All managed stocks in this region are assessed in NMFS's U.S. 2016 stock assessment report (SARs) (*e.g.,* NMFS 2016). All values presented in Table 2 are the most recent available at the time of publication and are available in the 2016 SAR (available online at *www.nmfs.noaa.gov/pr/sars*).

TABLE 2—MARINE MAMMALS POTENTIALLY PRESENT IN THE VICINITY OF NBPL

Species	Stock	ESA/MMPA status; strategic (Y/N) [1]	Stock abundance (CV, N_{min}, most recent abundance survey) [2]	PBR [3]	Annual M/SI [4]	Relative occurrence in San Diego Bay; season of occurrence
Order Cetartiodactyla—Cetacea—Superfamily Mysticeti (baleen whales)						
Family Eschrichtiidae						
Gray whale	Eastern North Pacific	-; N	20,990 (0.05; 20,125; 2011).	624	132	Occasional migratory visitor; winter.
Superfamily Odontoceti (toothed whales, dolphins, and porpoises)						
Family Delphinidae						
Bottlenose dolphin	California coastal	-; N	453 (0.06; 346; 2011)	2.7	≥2.0	Common; year-round.
Short-beaked common dolphin.	California/Oregon/Washington.	-; N	969,861 (0.17; 839,325; 2014).	8,393	≥40	Occasional; year-round (but more common in warm season).
Long-beaked common dolphin.	California	-; N	101,305 (0.49; 68,432; 2014).	657	≥35.4	Occasional; year-round (but more common in warm season).
Pacific white-sided dolphin.	California/Oregon/Washington.	-; N	26,814 (0.28; 21,195; 2014).	191	7.5	Uncommon; year-round.
Risso's dolphin	California/Oregon/Washington.	-; N	6,336 (0.32; 4,817; 2014).	46	≥3.7	Rare; year-round (but more common in cool season).
Order Carnivora—Superfamily Pinnipedia						
Family Otariidae (eared seals and sea lions)						
California sea lion	U.S.	-; N	296,750 (n/a; 153,337; 2011).	9,200	389	Abundant; year-round.
Family Phocidae (earless seals)						
Harbor seal	California	-; N	30,968 (n/a; 27,348; 2012).	1,641	43	Common; year-round.
Northern elephant seal	California breeding	-; N	179,000 (n/a; 81,368; 2010).	4,882	8.8	Rare; year-round.

[1] Endangered Species Act (ESA) status: Endangered (E), Threatened (T)/MMPA status: Depleted (D). A dash (-) indicates that the species is not listed under the ESA or designated as depleted under the MMPA. Under the MMPA, a strategic stock is one for which the level of direct human-caused mortality exceeds PBR (see footnote 3) or which is determined to be declining and likely to be listed under the ESA within the foreseeable future. Any species or stock listed under the ESA is automatically designated under the MMPA as depleted and as a strategic stock.

[2] CV is coefficient of variation; N_{min} is the minimum estimate of stock abundance. In some cases, CV is not applicable. For certain stocks of pinnipeds, abundance estimates are based upon observations of animals (often pups) ashore multiplied by some correction factor derived from knowledge of the species (or similar species) life history to arrive at a best abundance estimate; therefore, there is no associated CV. In these cases, the minimum abundance may represent actual counts of all animals ashore.

[3] Potential biological removal, defined by the MMPA as the maximum number of animals, not including natural mortalities, that may be removed from a marine mammal stock while allowing that stock to reach or maintain its optimum sustainable population size (OSP).

[4] These values, found in NMFS' SARs, represent annual levels of human-caused mortality plus serious injury from all sources combined (*e.g.,* commercial fisheries, subsistence hunting, ship strike). Annual M/SI often cannot be determined precisely and is in some cases presented as a minimum value.

All species that could potentially occur in the proposed survey areas are included in Table 2. As described below, all eight species (with nine managed stocks) temporally and spatially co-occur with the activity to the degree that take is reasonably likely to occur, and we have proposed authorizing it.

Gray Whale

Two populations of gray whales are recognized, Eastern and Western North Pacific (ENP and WNP). The two populations have historically been considered geographically isolated from each other; however, recent data from satellite-tracked whales indicates that there is some overlap between the stocks. Two WNP whales were tracked from Russian foraging areas along the Pacific rim to Baja California (Mate *et al.,* 2011), and, in one case where the satellite tag remained attached to the whale for a longer period, a WNP whale was tracked from Russia to Mexico and back again (IWC, 2012). Between 22–24 WNP whales are known to have occurred in the eastern Pacific through comparisons of ENP and WNP photo-identification catalogs (IWC 2012; Weller *et al.,* 2011; Burdin *et al.,* 2011), and WNP animals comprised 8.1 percent of gray whales identified during a recent field season off of Vancouver Island (Weller *et al.,* 2012). In addition, two genetic matches of WNP whales have been recorded off of Santa Barbara, CA (Lang *et al.,* 2011). More recently, Urban *et al.* (2013) compared catalogs of photo-identified individuals from Mexico with photographs of whales off Russia and reported a total of 21 matches. Therefore, a portion of the WNP population is assumed to migrate, at least in some years, to the eastern Pacific during the winter breeding season.

However, only ENP whales are expected to occur in the project area. The likelihood of any gray whale being exposed to project sound to the degree considered in this document is already low, as it would require a migrating whale to linger for an extended period of time, or for multiple migrating whales to linger for shorter periods of time. While such an occurrence is not unknown, it is uncommon. Further, of the approximately 20,000 gray whales migrating through the Southern California Bight, it is extremely unlikely that one found in San Diego Bay would be one of the approximately twenty WNP whales that have been documented in the eastern Pacific (less than one percent probability). The likelihood that a WNP whale would be exposed to elevated levels of sound from the specified activities is insignificant and discountable and WNP whales are not considered further in this document.

Gray whale transitory occurrence inside San Diego Bay is sporadic and unpredictable. A mean group size of 2.9 gray whales was reported for both coastal (16 groups) and non-coastal (15 groups) areas around Southern California Bight. The largest group reported was nine animals. The largest group reported by U.S. Navy (in 1998) was 27 animals (Carretta *et al.,* 2000). Gray whales are not expected in the project area except during the northward migration, when they are closest to the coast (Rice *et al.,* 1981).

Bottlenose Dolphin

The California coastal stock of bottlenose dolphin is distinct from the offshore population and is resident in the immediate (within 1 km of shore) coastal waters, occurring primarily between Point Conception, California, and San Quintin, Mexico. Occasionally, during warm-water incursions such as during the 1982–1983 El Niño events, their range extends as far north as San Francisco Bay (Carretta *et al.,* 2017). They are commonly found in groups of 2 to 15 individuals and in larger groups offshore.

Coastal bottlenose dolphins have occurred sporadically and in highly variable numbers and locations in San Diego Bay. Navy surveys showed that bottlenose dolphins were most commonly sighted in April, and there were more dolphins observed during El Niño years.

Pacific White-Sided Dolphin

Pacific white-sided dolphins are endemic to temperate waters of the North Pacific Ocean, and are common both on the high seas and along the continental margins (Carretta *et al.,* 2014). Off the U.S. west coast, Pacific white-sided dolphins occur primarily in shelf and slope waters. Sighting patterns from aerial and shipboard surveys conducted in California, Oregon and Washington suggest seasonal north-south movements, with animals found primarily off California during the colder water months and shifting northward into Oregon and Washington as water temperatures increase in late spring and summer (Carretta *et al.,* 2014).

Pacific white-sided dolphins are uncommon in San Diego Bay, but observations of this species increased during El Niño years. Monitoring during the Year 2 IHA documented 7 sightings of Pacific white-sided dolphins, comprising 27 individuals, with a mean group size of 3.85 individuals per sighting and an average of 0.28 individuals sighted per day of monitoring.

Common Dolphin

Short-beaked common dolphins are the most abundant cetacean off California and are widely distributed between the coast and at least 300 nmi offshore. In contrast, long-beaked common dolphins generally occur within 50 nmi of shore. Both species of common dolphin appear to shift their distributions seasonally and annually in response to oceanographic conditions and prey availability (Carretta *et al.,* 2016). The long-beaked species apparently prefers shallower, warmer water than the short-beaked common dolphin (Perrin 2009). Both tend to be more abundant in coastal waters during warm-water months (Bearzi 2005).

The occurrence of common dolphins inside San Diego Bay is uncommon (NAVFAC SW and POSD 2013). Small groups were observed briefly on several occasions in the northern part of the bay by Navy monitors during the IPP (May 2014). The animals were moving swiftly and could not be distinguished as to species, but the weight of evidence based on distributions of the two species and previous sightings of the long-beaked species near San Diego is that they were probably long-beaked common dolphins.

California Sea Lion

The entire population of California sea lions cannot be counted because all age and sex classes are never ashore at the same time. In lieu of counting all sea lions, pups are counted when all are ashore, in July during the breeding season, and the number of births is estimated from pup counts (Carretta *et al.,* 2016). The size of the population is then estimated from the number of births and the proportion of pups in the population. Based on these censuses, the U.S. stock has generally increased from the early 1900s, to a current estimate of 296,750 (Carretta *et al.,* 2016). There are indications that the California sea lion may have reached or is approaching carrying capacity, although more data are needed to confirm that leveling in growth persists (Carretta *et al.,* 2016).

The California sea lion is by far the most commonly-sighted pinniped species at sea or on land in the vicinity of NBPL and northern San Diego Bay. The Navy has conducted numerous marine mammal surveys overlapping the north San Diego Bay project area and the potential ZOI for impact and vibratory pile driving operations. California sea lions regularly occur on rocks, buoys and other structures, and especially on bait barges, although numbers vary greatly.

Harbor Seal

Harbor seals are considered abundant throughout most of their range from Baja California to the eastern Aleutian

Islands. Peak numbers of harbor seals haul-out on land during late May to early June, which coincides with the peak of their molt. Harbor seals do not make extensive pelagic migrations, but do travel hundreds of km on occasion to find food or suitable breeding areas (Carretta *et al.,* 2016). Based on likely foraging strategies, Grigg *et al.* (2009) reported seasonal shifts in harbor seal movements based on prey availability. In relationship to the entire California stock, harbor seals do not have a significant mainland California distribution south of Point Mugu.

Harbor seals are relatively uncommon within San Diego Bay. Sightings in the Navy transect surveys of northern San Diego Bay through March 2012, and were limited to individuals outside of the ZOI, on the south side of Ballast Point (TDI 2012b; Jenkins 2012). However, Navy marine mammal monitoring for another project conducted intermittently at Pier 122 from 2010–2014 documented from zero to 4 harbor seals near Pier 122 (within the ZOI) at various times, with the greatest number of sightings during April and May (Jenkins 2012; Bowman 2014). An individual harbor seal was also frequently sighted near NMAWC during 2014 (McConchie 2014).

Northern Elephant Seal

A complete population count of elephant seals is not possible because all age classes are not ashore simultaneously. The population is estimated to have grown at 3.8% annually since 1988 (Lowry *et al.,* 2014). Northern elephant seals breed and give birth in California (U.S.) and Baja California (Mexico), primarily on offshore islands. Populations of northern elephant seals in the U.S. and Mexico have recovered after being reduced to near extinction by hunting, undergoing a severe population bottleneck and loss of genetic diversity with the population reduced to only an estimated 10–30 individuals.

Northern elephant seals occur in the southern California bight, and have the potential to occur in San Diego Bay (NAVFAC SW and POSD 2013), but the only recent documentation of occurrence was of a single distressed juvenile observed on the beach south and inshore of the Fuel Pier during the second year IHA. Given the continuing, long-term increase in the population of northern elephant seals (Lowry *et al.,* 2014), there is an increasing possibility of occurrence in the project area.

Marine Mammal Hearing

Hearing is the most important sensory modality for marine mammals underwater, and exposure to anthropogenic sound can have deleterious effects. To appropriately assess the potential effects of exposure to sound, it is necessary to understand the frequency ranges marine mammals are able to hear. Current data indicate that not all marine mammal species have equal hearing capabilities (*e.g.,* Richardson *et al.,* 1995; Wartzok and Ketten 1999; Au and Hastings 2008). To reflect this, Southall *et al.* (2007) recommended that marine mammals be divided into functional hearing groups based on directly measured or estimated hearing ranges on the basis of available behavioral response data, audiograms derived using auditory evoked potential techniques, anatomical modeling, and other data. Note that no direct measurements of hearing ability have been successfully completed for mysticetes (*i.e.,* low-frequency cetaceans). Subsequently, NMFS (2016) described generalized hearing ranges for these marine mammal hearing groups. Generalized hearing ranges were chosen based on the approximately 65 decibel (dB) threshold from the normalized composite audiograms, with the exception for lower limits for low-frequency cetaceans where the lower bound was deemed to be biologically implausible and the lower bound from Southall *et al.* (2007) retained. The functional groups and the associated frequencies are indicated below (note that these frequency ranges correspond to the range for the composite group, with the entire range not necessarily reflecting the capabilities of every species within that group):

- *Low-frequency cetaceans (mysticetes):* Generalized hearing is estimated to occur between approximately 7 Hz and 35 kHz, with best hearing estimated to be from 100 Hz to 8 kHz;
- *Mid-frequency cetaceans (larger toothed whales, beaked whales, and most delphinids):* Generalized hearing is estimated to occur between approximately 150 Hz and 160 kHz, with best hearing from 10 to less than 100 kHz;
- *High-frequency cetaceans (porpoises, river dolphins, and members of the genera Kogia and Cephalorhynchus; including two members of the genus Lagenorhynchus, on the basis of recent echolocation data and genetic data):* Generalized hearing is estimated to occur between approximately 275 Hz and 160 kHz.
- *Pinnipeds in water; Phocidae (true seals):* Generalized hearing is estimated to occur between approximately 50 hertz (Hz) to 86 kilohertz (kHz), with best hearing between 1–50 kHz;
- *Pinnipeds in water; Otariidae (eared seals):* Generalized hearing is estimated to occur between 60 Hz and 39 kHz, with best hearing between 2–48 kHz.

The pinniped functional hearing group was modified from Southall *et al.* (2007) on the basis of data indicating that phocid species have consistently demonstrated an extended frequency range of hearing compared to otariids, especially in the higher frequency range (Hemilä *et al.,* 2006; Kastelein *et al.,* 2009; Reichmuth and Holt 2013).

For more detail concerning these groups and associated frequency ranges, please see NMFS (2016) for a review of available information. Nine marine mammal species (six cetacean and three pinniped (1 otariid and 2 phocid species)) have the reasonable potential to co-occur with the proposed survey activities. Please refer to Table 2. Of the cetacean species that may be present, one is classified as low-frequency cetaceans (*i.e.,* all mysticete species), and five are classified as mid-frequency cetaceans (*i.e.,* all delphinid and ziphiid species and the sperm whale).

Potential Effects of the Specified Activity on Marine Mammals and Their Habitat

This section includes a summary and discussion of the ways that components of the specified activity may impact marine mammals and their habitat. The *Estimated Take by Incidental Harassment* section later in this document includes a quantitative analysis of the number of individuals that are expected to be taken by this activity. The *Negligible Impact Analysis and Determination* section considers the content of this section, the *Estimated Take by Incidental Harassment* section, and the *Proposed Mitigation* section, to draw conclusions regarding the likely impacts of these activities on the reproductive success or survivorship of individuals and how those impacts on individuals are likely to impact marine mammal species or stocks.

We provided discussion of the potential effects of the specified activity on marine mammals and their habitat in our **Federal Register** notices of proposed authorization associated with the first- and second-year IHAs (78 FR 30873; May 23, 2013 and 79 FR 53026; September 5, 2014). The specified activity associated with this proposed IHA is substantially similar to those considered for the first- and second-year IHAs and the potential effects of the specified activity are the same as those identified in those documents. Therefore, we do not reprint the

information here but refer the reader to those documents.

In the aforementioned **Federal Register** notices, we also provided general background information on sound and marine mammal hearing and a description of sound sources and ambient sound and refer the reader to those documents. However, because certain terms are used frequently in this document, we provide brief definitions of relevant acoustic terminology below:

- *Sound pressure level (SPL):* Sound pressure is the force per unit area, usually expressed in microPascals (μPa), where one Pascal equals one Newton exerted over an area of one square meter. The SPL is expressed in dB as twenty times the logarithm to the base ten of the ratio between the pressure exerted by the sound to a referenced sound pressure. SPL is the quantity that is directly measured by a sound level meter. For underwater sound, SPL in dB is referenced to one microPascal (re 1 μPa), unless otherwise stated. For airborne sound, SPL in dB is referenced to 20 microPascals (re 20 μPa), unless otherwise stated.
- *Frequency:* Frequency is expressed in terms of oscillations, or cycles, per second. Cycles per second are commonly referred to as Hz. Typical human hearing ranges from 20 Hz to 20 kHz.
- *Peak sound pressure:* The instantaneous maximum of the absolute positive or negative pressure over the frequency range from 20 Hz to 20 kHz and presented in dB.
- *Root mean square (rms) SPL:* For impact pile driving, overall dB rms levels are characterized by integrating sound for each waveform across ninety percent of the acoustic energy in each wave and averaging all waves in the pile driving event. This value is referred to as the rms 90 percent. With this method, the time averaging per pulse varies.
- *Sound Exposure Level (SEL):* A measure of energy, specifically the dB level of the time integral of the squared-instantaneous sound pressure, normalized to a one second period. It is a useful metric for assessing cumulative exposure because it enables sounds of differing duration, to be compared in terms of total energy. The accumulated SEL (SEL_{cum}) is used to describe the SEL from multiple events (*e.g.,* many pile strikes). This can be calculated directly as a logarithmic sum of the individual single-strike SELs for the pile strikes that were used to install the pile.
- *Level Z weighted (unweighted), equivalent (LZ_{eq}):* LZ_{eq} is a value recorded by the SLM that represents SEL SPL over a specified time period or interval. The LZeq is most typically referred to in one-second intervals or over an entire event.
- *Level Z weighted (unweighted), fast (LZF_{max}):* LZF_{max} is a value recorded by the SLM that represents the maximum rms value recorded for any 125 millisecond time frame during each individual recording.

Estimated Take

This section provides an estimate of the number of incidental takes proposed for authorization through this IHA, which will inform both NMFS' consideration of whether the number of takes is ''small'' and the negligible impact determination. Harassment is the only type of take expected to result from these activities. Except with respect to certain activities not pertinent here, section 3(18) of the MMPA defines ''harassment'' as: Any act of pursuit, torment, or annoyance which (i) has the potential to injure a marine mammal or marine mammal stock in the wild (Level A harassment); or (ii) has the potential to disturb a marine mammal or marine mammal stock in the wild by causing disruption of behavioral patterns, including, but not limited to, migration, breathing, nursing, breeding, feeding, or sheltering (Level B harassment).

Authorized takes would be by Level B harassment only, in the form of disruption of behavioral patterns for individual marine mammals resulting from exposure to acoustic sources. Based on the nature of the activity and the anticipated effectiveness of the mitigation measures (*i.e.,* shutdown, soft start, *etc.*—discussed in detail below in *Proposed Mitigation* section), Level A harassment is neither anticipated nor proposed to be authorized.

As described previously, no mortality is anticipated or proposed to be authorized for this activity. Below we describe how the take is estimated.

Described in the most basic way, we estimate take by considering: (1) Acoustic thresholds above which NMFS believes the best available science indicates marine mammals will be behaviorally harassed or incur some degree of permanent hearing impairment; (2) the area or volume of water that will be ensonified above these levels in a day; (3) the density or occurrence of marine mammals within these ensonified areas; and, (4) and the number of days of activities. Below, we describe these components in more detail and present the proposed take estimate.

Acoustic Thresholds

Using the best available science, NMFS has developed acoustic thresholds that identify the received level of underwater sound above which exposed marine mammals would be reasonably expected to be behaviorally harassed (equated to Level B harassment) or to incur PTS of some degree (equated to Level A harassment).

Level B Harassment for non-explosive sources—Though significantly driven by received level, the onset of behavioral disturbance from anthropogenic noise exposure is also informed to varying degrees by other factors related to the source (*e.g.,* frequency, predictability, duty cycle), the environment (*e.g.,* bathymetry), and the receiving animals (hearing, motivation, experience, demography, behavioral context) and can be difficult to predict (Southall *et al.,* 2007). Based on what the available science indicates and the practical need to use a threshold based on a factor that is both predictable and measurable for most activities, NMFS uses a generalized acoustic threshold based on received level to estimate the onset of behavioral harassment. NMFS predicts that marine mammals are likely to be behaviorally harassed in a manner we consider Level B harassment when exposed to underwater anthropogenic noise above received levels of 120 dB re 1 μPa (rms) for continuous (*e.g.* vibratory pile-driving, drilling) and above 160 dB re 1 μPa (rms) for non-explosive impulsive (*e.g.,* impact pile driving) or intermittent *(e.g.,* scientific sonar) sources.

The Navy's proposed activity includes the use of continuous (vibratory pile driving, demolition) and impulsive (impact pile driving) sources, and therefore the 120 and *160* dB re 1 μPa (rms) are applicable.

Level A harassment for non-explosive sources—NMFS's Technical Guidance for Assessing the Effects of Anthropogenic Sound on Marine Mammal Hearing (NOAA 2016) identifies dual criteria to assess auditory injury (Level A harassment) to five different marine mammal groups (based on hearing sensitivity) as a result of exposure to noise from two different types of sources (impulsive or non-impulsive). The Navy's construction project includes the use of impulsive (impact pile driving) and non-impulsive (vibratory pile driving) sources.

These thresholds were developed by compiling and synthesizing the best available science and soliciting input multiple times from both the public and peer reviewers to inform the final product, and are provided in the table below. The references, analysis, and methodology used in the development of the thresholds are described in NMFS 2016 Technical Guidance, which may be accessed at: *http://*

www.nmfs.noaa.gov/pr/acoustics/guidelines.htm.

TABLE 3—THRESHOLDS IDENTIFYING THE ONSET OF PERMANENT THRESHOLD SHIFT

Hearing Group	PTS onset acoustic thresholds * (received level)	
	Impulsive	Non-impulsive
Low-frequency cetaceans	*Cell 1:* Lpk,flat: 219 dB; LE,LF,24h: 183 dB	*Cell 2:* LE,LF,24h: 199 dB.
Mid-frequency cetaceans	*Cell 3:* Lpk,flat: 230 dB; LE,MF,24h: 185 dB	*Cell 4:* LE,MF,24h: 198 dB.
High-frequency cetaceans	*Cell 5:* Lpk,flat: 202 dB; LE,HF,24h: 155 dB	*Cell 6:* LE,HF,24h: 173 dB.
Phocid Pinnipeds (underwaters)	*Cell 7:* Lpk,flat: 218 dB; LE,PW,24h: 185 dB	*Cell 8:* LE,PW,24h: 201 dB.
Otariid Pinnipeds (underwater)	*Cell 9:* Lpk,flat: 232 dB; LE,OW,24h: 203 dB	*Cell 10:* LE,OW,24h: 219 dB.

NMFS 2016.

Ensonified Area

Here, we describe operational and environmental parameters of the activity that will feed into identifying the area ensonified above the acoustic thresholds.

The intensity of pile driving or sounds is greatly influenced by factors such as the type of piles, hammers, and the physical environment in which the activity takes place. For the installation of 30-in steel piles and pile cutting activities, acoustic monitoring during the first and second IHA periods (NAVFAC 2015) resulted in empirical data that are directly applicable to the fifth IHA period in terms of the activities and the location, depth, sizes and types of piles.

Table 4 identifies the sound source levels that are used in evaluating impact and vibratory pile driving and extraction in the current IHA application. Sound levels for the hydraulic pile cutter, diamond saw caisson cutting, and pile jetting were measured during the fourth IHA period (NAVFAC SW 2017). No acoustic data are available from the vibratory driving of 16-in concrete piles, so the data for vibratory installation of 30-in steel piles from the second IHA period are used as a conservative proxy (NAVFAC SW 2015). Finally, SPLs were measured for the impact driving of 16-in poly-concrete piles during the third IHA monitoring period (NAVFAC SW 2016a), and are used in this application for the same activities.

TABLE 4—UNDERWATER SOUND PRESSURE LEVELS FROM SIMILAR IN SITU MONITORED CONSTRUCTION ACTIVITIES FROM PREVIOUS YEARS

Project and location	Pile size and type	Method	Water depth	Measured sound pressure levels (rms) at 10 m (dB re 1 μPa)	
				Mean [1]	Max [2]
NBPL Fuel Pier, San Diego, CA	13 to 24-in concrete	Hydraulic pile cutting	9 m (30 ft)	145	165.3
NBPL Fuel Pier, San Diego, CA	66- and 84-in steel caisson	Diamond saw cutting	9 m (30 ft)	149	155.6
NBPL Fuel Pier, San Diego, CA	24-in concrete	Jetting	9 m (30 ft)	155	159.9
NBPL Fuel Pier, San Diego, CA	30-in Steel Pipe	Vibratory	9 m (30 ft)	162.5	[3] 162.5
NBPL Fuel Pier, San Diego, CA	16-in Poly-Concrete	Impact	9 m (30 ft)	188.9	[4] 195

[1] Mean source levels used from data from previous monitoring reports (NAVFAC SW 2015, 2016a, 2017). Mean source levels were used to calculate Level B ZOIs.

[2] Maximum source levels used from data from previous monitoring reports (NAVFAC SW 2015, 2016a, 2017). Max source levels were used to calculate Level A ZOIs. Maximum source levels used were proposed by the Navy.

[3] Mean source levels for 30-in steel pipe piles were used as a proxy to calculate ZOIs for vibratory driving of 16-in concrete guide piles (NAVFAC SW 2015).

[4] The maximum source level is included for reference only. The distance to the Level B ZOI is based on *in situ* data collected for 16-in poly-concrete piles and was documented in NAVFAC SW (2016a).

Scarce data exists on airborne and underwater noise levels associated with vibratory hammer extraction. However, it can reasonably be assumed that vibratory extraction emits SPLs that are no higher than SPLs caused by vibratory hammering of the same materials, and results in lower SPLs than caused by impact hammering comparable piles. For this application, the same value (162.5 dB re 1μPa) that was obtained for vibratory hammering of the 30-in steel piles at the Fuel Pier (NAVFAC SW 2015) is used for the vibratory hammering of 16-in round concrete piles at NMAWC. None of the peak SPLs for the various sound sources reach the injury thresholds identified in the new NMFS (2016) Technical Guidance; therefore, injury from peak sound levels is not considered further.

Table 6 provides the calculated areas of Level A and Level B ZOIs associated with the impulsive and continuous sounds that are anticipated during the fifth-year IHA period. Table 5 provides the data that were used to calculate the distances to the Level A and B ZOIs presented in Table 6. It should be noted that the ZOI for Level A harassment would be closely monitored and subject to shutdowns if a marine mammal enters the area. The ZOI areas and maximum distances for the activities at the fuel pier and NMAWC are shown in Figures 6–1 and 6–2, respectively of the Navy's application. The figures reflect the conventional assumption that the natural or manmade shoreline acts as a barrier to underwater sound. It is generally accepted practice to model underwater sound propagation from pile driving as continuing in a straight line past a shoreline projection such as Ballast Point (Dahl 2012). Similarly, it is reasonable to assume that project sound would not propagate east of Zuniga Jetty (Dahl 2012).

All of the ZOIs for potential Level A acoustic harassment (Table 6) would be buffered and encompassed by a larger shutdown zone. For example, the ZOIs for potential Level A acoustic harassment to pinnipeds from impact pile driving (Table 6) would be contained within a 60 m (196 ft) shutdown zone. For impact pile driving at NMAWC, two methods identified in NMFS (2016) were evaluated to determine the most conservative distances to the Level A ZOIs using: (1) rms SPL source levels; and (2) single strike equivalent SEL. The calculations showed that the first method was the most conservative and this method was subsequently used to determine the distances to the Level A ZOIs (Table 5). In all Level A ZOI calculations, the default values for the weighting factor adjustment and practical spreading for propagation loss were used (see Appendix A of the Navy's application).

TABLE 5—DATA USED TO CALCULATE DISTANCES TO LEVEL B ZOIS

Activity	Impact pile driving	Vibratory pile driving	Pile jetting	Caisson cutting	Pile clipping
References for Source Level and Duration.	Year 3 report #1 (NAVFAC SW 2016a).	Year 2 report (NAVFAC SW 2015).	Year 4 report (NAVFAC SW 2017).	Year 3 report #1 (NAVFAC SW 2016a).	Year 4 report (NAVFAC SW 2017).
Size & Type of Piles used for Source Data.	16-in poly-concrete piles.	30-in steel piles	24x30-in concrete piles.	84-in caissons	24-in concrete piles.
Source Level (rms SPL).	188.9	162.5	159.9	155.6	165.3.
Distance to Level B ZOI (m).	270	1,848	1,165	631	2,511.

The Level B ZOIs and distances are based on the validated SPLs directly measured during the IHA monitoring (NAVFAC SW 2014–2017), as available. For example, the distance to the Level B ZOI for impact driving of 16-in poly-concrete piles was 270 m (886 ft) during Year 3 monitoring (NAVFAC SW 2016a). In cases where monitoring data are not available to empirically measure the extent of the Level B ZOI (activities at NMAWC), ''practical spreading loss'' from the source at 10 m has been assumed (15 log[distance/10]) and used to calculate the maximum extent of the ZOI based on the applicable threshold. Computed distances to the threshold for acoustic disturbance from non-impulsive sources are based on the distances at which the project sound source declines to ambient. Because the mean ambient sound levels in San Diego Bay range from approximately 128 to 130 dB rms (NAVFAC SW 2015), the 120 dB acoustic threshold for the Level B ZOIs are based on an approximate value between 128 and 129 dB. The distances for all activities producing sound at NMAWC will be verified via hydrophone during project activities.

TABLE 6—CALCULATED MAXIMUM AREAS OF ZOIS AND DISTANCES TO RELEVANT THRESHOLDS

Activity	Measured/calculated distances to thresholds (m) and areas of ZOIs (m^2 or km^2)							
	Underwater						Airborne	
	Level A[1 2 3]				Level B[4]		Level B	
	LF	MF	PW	OW	160 dB	120 dB[5]	100 dB[6]	90 dB[6]
Old Fuel Pier and Temporary Mooring Dolphin Demolition								
66-inch and 84-inch caissons (Diamond saw cutting).	3.6 m 41 m^2	0.3 m <1 m^2	2.2 m 15 m^2	0.2m <1 m^2	N/A	631 m 0.7157 km^2	N/A	
Concrete piles (Pile clipping)	1.2 m 4 m^2	0.1 m <1 m^2	0.7 m < 1 m^2	0.0 m 0 m^2	N/A	2,511 m 4.4512 km^2		
NMAWC Construction and Demolition								
16-inch concrete piles (Vibratory extraction/driving)[8].	8.3 m 216 m^2	0.7 m <1 m^2	5.1 m 82 m^2	0.4 m <1 m^2	N/A	1,848 m 2.4473 km^2	42 m 5,503 m^2	149 m 69,646 m^2
16-inch concrete piles (Impact driving)[9]	63.4 m 0.0126 km^2	2.3 m 17 m^2	33.9 m 3,610 m^2	2.5 m 20 m^2	270 m 0.1408 km^2	N/A		
16-inch concrete piles (Jetting pile extraction).	3.9 m 47.8 m^2	0.3 m <1 m^2	2.4 m 18 m^2	0.2 m <1 m^2	N/A	1,165m 1.4268 km^2	N/A	

[1] If measured value thresholds are less than 10 m (33 ft), a minimum monitoring distance of 10 m (33 ft) would be implemented.
[2] Based on measured mean source levels. The relevant data have been included in Appendix A of the Navy's application, which provides information from previous years' data collected as part of the Fuel Pier Project (NAVFAC SW 2015, 2016a, 2017).
[3] LF = Low-frequency cetaceans; MF = Mid-frequency cetaceans; PW = Phocid pinnipeds; OW = Otariid pinnipeds. The high-frequency cetacean hearing group (HF) is omitted, because no species in the hearing group occur in, or around, the Project area.
[4] Based on measured maximum source levels, unless otherwise stated. The relevant data have been included in Appendix A, which provides information from previous years' data collected as part of the Fuel Pier Project (NAVFAC SW 2015, 2016a, 2017).
[5] Average ambient sound levels in San Diego Bay are approximately 128 to 130 dB rms (NAVFAC SW 2015), and all 120 dB Level B ZOIs are based on an approximate value between 128 and 129, which represents ambient levels in the Bay.
[6] Airborne ZOIs based on conservative representative data (collected during 30-inch vibratory pile driving from IHA #4). Airborne noise levels did not exceed thresholds during IHA #4 monitoring of demolition activities.
[7] Plasma torch noise levels are not expected to exceed underwater or airborne regulatory thresholds.
[8] Based on conservative representative source levels of 162.5 dB rms (30-inch steel vibratory pile driving, NAVFAC SW 2015).

Airborne Sound

Although sea lions are known to haul-out regularly on man-made objects in the vicinity of the project site (see Figure 4–1 of the Navy's application), and harbor seals are occasionally observed hauled out on rocks along the shoreline in the vicinity of the project site, none of these are within the ZOIs for airborne sound, and we believe that incidents of take resulting solely from airborne sound are unlikely. The zones for sea lions are within the minimum shutdown zone defined for underwater sound and, although the zones for harbor seals are larger, they have not been observed to haul out as readily on man-made structure in the immediate vicinity of the project site. There is a possibility that an animal could surface in-water, but with head out, within one of the defined zones and thereby be exposed to levels of airborne sound that we associate with harassment, but any such occurrence would likely be accounted for in our estimation of incidental take from underwater sound.

We generally recognize that pinnipeds occurring within an estimated airborne harassment zone, whether in the water or hauled out, could be exposed to airborne sound that may result in behavioral harassment. However, any animal exposed to airborne sound above the behavioral harassment threshold is likely to also be exposed to underwater sound above relevant thresholds (which are typically in all cases larger zones than those associated with airborne sound). Thus, the behavioral harassment of these animals is already accounted for in these estimates of potential take. Multiple incidents of exposure to sound above NMFS' thresholds for behavioral harassment are not believed to result in increased behavioral disturbance, in either nature or intensity of disturbance reaction. Therefore, we do not believe that authorization of incidental take resulting from airborne sound for pinnipeds is warranted, and airborne sound is not discussed further here. Distances associated with airborne sound and shown in Table 5 are for reference only.

When NMFS Technical Guidance (2016) was published, in recognition of the fact that ensonified area/volume could be more technically challenging to predict because of the duration component in the new thresholds, we developed a User Spreadsheet that includes tools to help predict a simple isopleth that can be used in conjunction with marine mammal density or occurrence to help predict takes. We note that because of some of the assumptions included in the methods used for these tools, we anticipate that isopleths produced are typically going to be overestimates of some degree, which will result in some degree of overestimate of Level A take. However, these tools offer the best way to predict appropriate isopleths when more sophisticated 3D modeling methods are not available, and NMFS continues to develop ways to quantitatively refine these tools, and will qualitatively address the output where appropriate. For stationary sources such as vibratory pile driving, NMFS User Spreadsheet predicts the closest distance at which, if a marine mammal remained at that distance the whole duration of the activity, it would not incur PTS. Inputs used in the User Spreadsheet, and the resulting isopleths are reported below.

TABLE 7—LEVEL A USER SPREADSHEET INPUT

	Impact pile driving	Vibratory pile driving	Caisson cutting	Pile clipping	Pile jetting
References for Source Level and Duration.	Year 3 report #1 (NAVFAC SW 2016a).	Year 2 report (NAVFAC SW 2015).	Year 3 report #1 (NAVFAC SW 2016a).	Year 4 report (NAVFAC SW 2017).	Year 4 report (NAVFAC SW 2017).
Spreadsheet Tab Used ...	(E.1) Impact pile driving	(A.) Non-Impulse Stat-Cont.	(A.) Non-Impulse Stat-Cont.	(A.) Non-Impulse Stat-Cont.	(A.) Non-Impulse Stat-Cont.
Source Level (Single Strike/shot SEL).	188.9	162.5	149	145	155.
Weighting Factor Adjustment (kHz).	2	2.5	2.5	2.5	2.5.
(a) Activity Duration (h) within 24-h period.	0.71	0.95	6	2.82	1.74.
Propagation (xLogR)	15	15	15	15	15.
Distance of source level measurement (m).	10	10	10	10	10.
Pulse duration (sec) [1]	0.03	n/a	n/a	n/a	n/a.
Number of strikes in 1 h ..	193	n/a	n/a	n/a	n/a.

[1] Pulse duration was measured in previous construction years and the average pulse duration was 0.03 at 10 m (NAVFAC SW 2016a).

Marine Mammal Occurrence

In this section we provide the information about the presence, density, or group dynamics of marine mammals that will inform the take calculations.

For all species, the best scientific information available was considered for use in the marine mammal take assessment calculations. Although various regional offshore surveys for marine mammals have been conducted, it is unlikely that these data would be representative of the species or numbers that may be encountered in San Diego Bay. However, the Navy has conducted a large number of ongoing site-specific marine mammal surveys during appropriate seasons (*e.g.,* Merkel and Associates 2008; Johnson 2010, 2011; Lerma 2012, 2014). Whereas analyses for the first-year IHA relied on surveys conducted from 2007–12, continuing surveys by the Navy have generally indicated increasing abundance of all species and the second-year IHA relied on 2012–14 survey data. In addition, the Navy has developed estimates of marine mammal densities in waters associated with training and testing areas (including Hawaii-Southern California) for the Navy Marine Species Density Database (NMSDD). A technical report (Hanser *et al.,* 2015) describes methodologies and available information used to derive these densities, which are based upon the best available information, except where specific local abundance information is available and applicable to a specific action area. The document is publicly available online at: *nwtteis.com/DocumentsandReferences/NWTTDocuments/SupportingTechnicalDocuments.aspx* (accessed July 13, 2017).

Year 2 project monitoring showed even greater abundance of certain species, and we consider all of these data in order to provide the most up-to-date estimates for marine mammal abundances during the period of this proposed IHA. Although Years 3 and 4 project monitoring showed declines in marine mammal abundance in the vicinity of the project, we retain prior density estimates as a conservative measure for estimating exposure.

Density information is shown in Table 9. These data are from dedicated line-transect surveys, required project marine mammal monitoring, opportunistic observations for more rarely observed species (see Figures 3–1 through 3–5 of the Navy's application), or the NMSDD.

Take Calculation and Estimation

Here we describe how the information provided above is brought together to produce a quantitative take estimate.

The following assumptions are made when estimating potential incidences of take:

- All marine mammal individuals potentially available are assumed to be present within the relevant area, and thus incidentally taken;
- An individual can only be taken once during a 24-h period;
- The assumed ZOIs and days of activity are as shown in Table 5; and,
- Exposures to sound levels at or above the relevant thresholds equate to take, as defined by the MMPA.

In this case, the estimation of marine mammal takes uses the following calculation:

Exposure estimate = n * ZOI * days of total activity

Where:

n = density estimate used for each species/season.

ZOI = sound threshold ZOI area; the area encompassed by all locations where the SPLs equal or exceed the threshold being evaluated.

The ZOI impact area is estimated using the relevant distances in Table 5, assuming that sound radiates from a central point in the water column slightly offshore of the existing pier and taking into consideration the possible affected area due to topographical constraints of the action area (*i.e.,* radial distances to thresholds are not always reached).

TABLE 8—AREAS OF ACOUSTIC INFLUENCE AND DAYS OF ACTIVITY

Activity	Number of days	ZOI (km^2)
66-inch and 84-inch caissons (Diamond saw cutting)	50	0.7157
Concrete piles (Pile clipping)	100	4.4512
16-inch concrete piles (Vibratory extraction/driving) [1]	25	2.4473
16-inch concrete piles (Jetting pile extraction)	15	1.4268

[1] We assume that impact driving of 16-in concrete piles would always occur on the same day as vibratory driving of the same piles. Therefore, the impact driving ZOI (0.1408 km^2) would always be subsumed by the vibratory driving ZOI.

There are a number of reasons why estimates of potential incidents of take may be conservative, assuming that available density and estimated ZOI areas are accurate. We assume, in the absence of information supporting a more refined conclusion, that the output of the calculation represents the number of individuals that may be taken by the specified activity. In fact, in the context of stationary activities such as pile driving and in areas where resident animals may be present, this number more realistically represents the number of incidents of take that may accrue to a smaller number of individuals. While pile driving can occur any day throughout the period of validity, and the analysis is conducted on a per day basis, only a fraction of that time (typically a matter of hours on any given day) is actually spent pile driving. The potential effectiveness of mitigation measures in reducing the number of takes is typically not quantified in the take estimation process. For these reasons, these take estimates may be conservative. See Table 9 for total estimated incidents of take.

California Sea Lion

During the second IHA period, an average of 90.35 California sea lions were seen per day within the maximum ZOI for pile driving, an area of 5.6752 km^2 extending 3,000 m from the Fuel Pier. This equates to a density of 15.9201/km^2. This density is used to estimate numbers of takes within the different ZOIs. NMFS estimates 8,971 Level B takes for this species. The maximum extents of the potential acoustic Level A ZOIs for cumulative exposure from all of the activities are much less than 10 m from the source, and therefore the 60-m shutdown zone will reduce the chance for Level A take. As a result, no Level A take of California sea lions is anticipated nor proposed to be authorized.

Harbor Seal

Sightings of harbor seals averaged 2.83 individuals per day during the period of the second IHA (NAVFAC SW 2015), a density of 0.4987/km^2 within the maximum ZOI for pile driving. This density is used to estimate numbers of takes within the different ZOIs. NMFS estimates 281 Level B takes for this species. The maximum extent of the potential acoustic Level A ZOI for cumulative exposure from impact pile driving extends 34 m from the source; for all other activities, the Level A ZOIs are much less than 10 m from the source, therefore a 60-m shutdown zone will be in place to avoid Level A takes to harbor seals. Level A takes are not anticipated nor proposed for authorization.

Northern Elephant Seal

Only a single individual elephant seal was sighted during the second IHA period (NAVFAC SW 2015), but with increasing numbers (Carretta *et al.,* 2016), they are considered a reasonable possibility to occur more frequently during the fifth IHA period. The regional density estimate of 0.0760/km^2 (Navy 2017) is assumed for the project area. This density is used to estimate numbers of takes within the different ZOIs. NMFS estimates 43 Level B takes for this species. Potential takes would likely involve single individuals that are on the shoreline or structures at the identified location, or swimming in the vicinity, most likely near the mouth of the bay. The maximum extent of the potential acoustic Level A ZOI for cumulative exposure from impact pile driving extends 34 m from the source; for all other activities, the Level A ZOIs are much less than 10 m from the source, therefore a shutdown will be in place to avoid Level A takes to harbor seals. Level A takes are not anticipated nor proposed for authorization.

Bottlenose Dolphin

Coastal bottlenose dolphins can occur at any time of year in northern San Diego Bay. Numbers sighted have been highly variable but have increased in recent years (NAVFAC SW 2014, 2015). During the second IHA period, an average of 7.09 individuals was seen per day, a density of 1.2493/km^2. This density is used to estimate numbers of takes within the different ZOIs. NMFS estimates 704 Level B takes for this species. The maximum extents of the potential acoustic Level A ZOIs for cumulative exposure from all of the activities are much less than 10 m from

the source, and therefore the minimum 10 m shutdown will reduce the chance for Level A take. As a result, no Level A take of bottlenose dolphins is anticipated nor proposed to be authorized.

Common Dolphin

An average of 8.67 common dolphins was seen per day, a density of 1.5277/km² within the maximum ZOI, during the second IHA period (NAVFAC SW 2015). This density is considerably higher than the regional density estimate for long-beaked common dolphins—the species most likely to occur (Navy 2017), but is reasonable for the project area given the group sizes observed for these species. Barlow (2010) reported average group sizes in southern California of 122 for short-beaked common dolphins and 195 for long-beaked common dolphins, and during the second IHA period, groups of approximately 170 and 300 individuals entered the project area on different occasions (NAVFAC SW 2015). Considering the possibility for one or more large groups of common dolphins to enter San Diego Bay during in-water activities and the fact that the Level B ZOIs will extend completely across the bay during pile driving, the density estimate is considered appropriate. A density of 1.5277/km² is used to estimate numbers of takes within the different ZOIs. NMFS estimates 861 Level B takes for this species. The maximum extents of the potential acoustic Level A ZOIs for cumulative exposure from all of the activities are much less than 10 m from the source, and therefore the shutdown will reduce the chance for Level A take. As a result, no Level A take of bottlenose dolphins is anticipated nor proposed to be authorized.

Pacific White-Sided Dolphin

Pacific white-sided dolphins are more commonly seen offshore, but were documented in the project area on several occasions during the second IHA period. An average of 0.28 individuals per day was seen during the second IHA period (NAVFAC SW 2015), a density of 0.0493/km² within the maximum ZOI. This density is used to estimate numbers of takes within the different ZOIs. NMFS estimates 28 Level B takes for this species. The maximum extents of the potential acoustic Level A ZOIs for cumulative exposure from all of the activities are much less than 10 m from the source, and therefore the shutdown will reduce the chance for Level A take. As a result, no Level A take of bottlenose dolphins is anticipated nor proposed to be authorized.

Risso's Dolphin

While there have been no sightings of Risso's dolphin within the project area, the species is considered a reasonable possibility for the fifth IHA period given recent El Niño conditions (Shane 1995) and its abundance in Southern California coastal waters (Jefferson *et al.* 2014). The upper limit of the regional density estimate, 0.2029/km² (Navy 2017), is used to estimate numbers of takes within the different ZOIs. NMFS estimates 114 Level B takes for this species. The maximum extents of the potential acoustic Level A ZOIs for cumulative exposure from all of the activities are much less than 10 m from the source, and therefore the shutdown will reduce the chance for Level A take. As a result, no Level A take of bottlenose dolphins is anticipated nor proposed to be authorized.

Gray Whale

Gray whale occurrence within northern San Diego Bay is sporadic and would likely consist of one-few individuals that venture close to, or enter the bay for a brief period, and then continue on their migration. A density estimate based on the rare sightings of gray whales near the mouth of the bay during the second IHA period (NAVFAC SW 2015), would be less than 0.01/km², which is slightly less than the regional density estimate of 0.0179/km² in southern California waters during winter-spring (Navy 2017). The regional density estimate is applied here as a reasonable estimate given the possibility of animals moving closer to shore and entering the mouth of the bay during the fifth IHA period. This density is used to estimate numbers of takes within the different ZOIs. NMFS estimates 10 Level B takes for this species. The maximum extent of the potential acoustic Level A ZOI for cumulative exposure from impact pile driving extends 63 m from the source; for all other activities, the Level A ZOIs are much less than 10 m from the source. Gray whales are not expected to occur that close to the source; however, the Navy has proposed a minimum of 10 m (100 m for impact driving) shutdown will be in place to avoid Level A takes to gray whales. Level A takes are not anticipated nor proposed for authorization.

TABLE 9—CALCULATIONS FOR INCIDENTAL TAKE ESTIMATION

Species	Density	Diamond saw cutting of 66-inch and 84-inch caissons	Pile clipping concrete piles	Vibratory extraction/ driving of 16-inch concrete piles	Jetting pile extraction of 16 in concrete piles	Total Level B takes *	Total proposed authorized takes (% of total stock)
California sea lion	15.9201	570	7086	974	341	8,971	3.023
Harbor seal	0.4987	18	222	31	11	281	0.907
Northern elephant seal	0.076	3	34	5	2	43	0.024
Bottlenose dolphin	1.2493	45	556	76	27	704	[2] 155
Common dolphin	1.5277	55	680	93	33	861	[3] 0.088; [4] 0.85
Pacific white-sided dolphin	0.0493	2	22	3	1	28	0.104
Risso's dolphin	0.2027	7	90	12	4	114	1.799
Gray whale	0.0179	1	8	1	0	10	0.048

* Due to rounding of takes to the nearest whole number of animals, (which occurs at the very end, not per activity), totals may not always equal the sum of the takes from individual activities.

[1] We assume that impact driving of steel piles would occur on the same day as vibratory driving of the same piles and that the zone for vibratory driving would always subsume the zone for impact driving. Therefore, separate estimates are not provided for impact driving of steel piles.

[2] The proposed numbers of authorized take for bottlenose dolphins are higher relative to the total stock abundance estimate and would not represent small numbers if a significant portion of the take was for a new individual. However, these numbers represent the estimated incidents of take, not the number of individuals taken. That is, it is likely that a relatively small subset of California coastal bottlenose dolphins would be incidentally harassed by project activities.

[3] SB = short-beaked common dolphin.

[4] LB = long-beaked common dolphin.

Proposed Mitigation

In order to issue an IHA under section 101(a)(5)(D) of the MMPA, NMFS must set forth the permissible methods of taking pursuant to such activity, and other means of effecting the least practicable impact on such species or stock and its habitat, paying particular attention to rookeries, mating grounds, and areas of similar significance, and on the availability of such species or stock for taking for certain subsistence uses (latter not applicable for this action). NMFS regulations require applicants for incidental take authorizations to include information about the availability and feasibility (economic and technological) of equipment, methods, and manner of conducting such activity or other means of effecting the least practicable adverse impact upon the affected species or stocks and their habitat (50 CFR 216.104(a)(11)).

In evaluating how mitigation may or may not be appropriate to ensure the least practicable adverse impact on species or stocks and their habitat, as well as subsistence uses where applicable, we carefully consider two primary factors:

(1) The manner in which, and the degree to which, the successful implementation of the measure(s) is expected to reduce impacts to marine mammals, marine mammal species or stocks, and their habitat. This considers the nature of the potential adverse impact being mitigated (likelihood, scope, range). It further considers the likelihood that the measure will be effective if implemented (probability of accomplishing the mitigating result if implemented as planned) the likelihood of effective implementation (probability implemented as planned). And;

(2) The practicability of the measures for applicant implementation, which may consider such things as cost, impact on operations, and, in the case of a military readiness activity, personnel safety, practicality of implementation, and impact on the effectiveness of the military readiness activity.

The mitigation strategies described below largely follow those required and successfully implemented under the first four IHAs associated with this project. For this proposed IHA, data from acoustic monitoring conducted during the first four years of work was used to estimate zones of influence (ZOIs; see *Estimated Take by Incidental Harassment*); these values were used to develop mitigation measures for pile driving activities at NBPL. The ZOIs effectively represent the mitigation zone that would be established around each pile to minimize Level A harassment to marine mammals, while providing estimates of the areas within which Level B harassment might occur. In addition, the Navy has defined buffers to the estimated Level A harassment zones to further reduce the potential for Level A harassment. In addition to the measures described later in this section, the Navy would conduct briefings between construction supervisors and crews, marine mammal monitoring team, acoustic monitoring team, and Navy staff prior to the start of all pile driving activity, and when new personnel join the work, in order to explain responsibilities, communication procedures, marine mammal monitoring protocol, and operational procedures.

Monitoring and Shutdown for Pile Driving

The following measures would apply to the Navy's mitigation through shutdown and disturbance zones:

Shutdown Zone—For all pile driving and removal activities, the Navy will establish a shutdown zone intended to contain the area in which SPLs equal or exceed the calculated Level A zones (refer to table). The purpose of a shutdown zone is to define an area within which shutdown of activity would occur upon sighting of a marine mammal (or in anticipation of an animal entering the defined area), thus preventing injury of marine mammals (serious injury or death are unlikely outcomes even in the absence of mitigation measures). Estimated radial distances to the relevant thresholds are shown in Table 5. For certain activities, the shutdown zone would not exist because source levels indicate that the radial distance to the threshold would be less than 10 m. However, a minimum shutdown zone of 10 m will be established during all pile driving and removal activities, regardless of the estimated zone. In addition the Navy proposes to effect a buffered shutdown zone that is intended to significantly reduce the potential for Level A harassment given that, in particular, California sea lions are quite abundant in the project area and bottlenose dolphins may surface unpredictably and move erratically in an area with a large amount of construction equipment. These buffers are approximately double the distance to the Level A ZOI. These zones are also shown in Table 10. These precautionary measures are intended to prevent the already unlikely possibility of physical interaction with construction equipment and to establish a precautionary minimum zone with regard to acoustic effects.

TABLE 10—SHUTDOWN ZONES FOR LEVEL A ZOIS AND MONITORING ZONES FOR LEVEL B ZONES

Activity	Monitored distances to thresholds (meters [feet])					
	Underwater					
	Level A (shutdown)				Level B	
	LF [1]	MF [1]	PW [1]	OW [1]	160 dB	120 dB [2]
Old Fuel Pier and Temporary Mooring Dolphin Demolition						
66-inch and 84-inch caissons (Diamond saw cutting)	10				N/A	631
Concrete piles (Pile clipping)	10				N/A	2,511
NMAWC Construction and Demolition						
16-inch concrete piles (Vibratory extraction/driving)	20 [4]		10		N/A	1,848
16-inch concrete piles (Impact driving)	100 [5]		60 [6]		857.7	N/A
16-inch concrete piles (Jetting pile extraction)	10				N/A	1,165

TABLE 10—SHUTDOWN ZONES FOR LEVEL A ZOIS AND MONITORING ZONES FOR LEVEL B ZONES—Continued

Activity	Monitored distances to thresholds (meters [feet])					
	Underwater					
	Level A (shutdown)				Level B	
	LF [1]	MF [1]	PW [1]	OW [1]	160 dB	120 dB [2]
16-inch concrete piles (Pile dead-pull)	10				N/A	

[1] LF = Low-frequency cetaceans; MF = Mid-frequency cetaceans; PW = Phocid pinnipeds; OW = Otariid pinnipeds. The high-frequency cetacean hearing group (HF) is omitted, because no species in the hearing group occur in, or around, Project area.

[2] Mean ambient sound levels in San Diego Bay are approximately 128 dB rms (NAVFAC SW 2015), and all 120 dB Level B ZOIs are based on the ambient value. The distances for all activities producing sound at NMAWC will be verified via hydrophone during project activities.

[3] Airborne noise levels did not exceed regulatory thresholds during previous IHAs. No airborne monitoring will take place for diamond saw cutting of caissons, plasma torch cutting of temporary mooring dolphin 30-inch steel piles, jetting or dead-pull extraction of concrete piles.

[4] Includes buffer of calculated Level A threshold out to 20 m (65.6 ft).

[5] Includes buffer of calculated Level A threshold out to 100 m (328 ft).

[6] Includes buffer of calculated Level A threshold out to 60 m (328 ft).

Disturbance Zone—Disturbance zones are the areas in which SPLs equal or exceed 160 and 120 dB rms (for impulse and continuous sound, respectively). Disturbance zones provide utility for monitoring conducted for mitigation purposes (*i.e.,* shutdown zone monitoring) by establishing monitoring protocols for areas adjacent to the shutdown zones. Monitoring of disturbance zones enables observers to be aware of and communicate the presence of marine mammals in the project area but outside the shutdown zone and thus prepare for potential shutdowns of activity. However, the primary purpose of disturbance zone monitoring is for documenting incidents of Level B harassment; disturbance zone monitoring is discussed in greater detail later (see *Proposed Monitoring and Reporting*). Nominal radial distances for disturbance zones are shown in Table 10.

In order to document observed incidents of harassment, monitors record all marine mammal observations, regardless of location. The observer's location, as well as the location of the pile being driven, is known from a GPS. The location of the animal is estimated as a distance from the observer, which is then compared to the location from the pile. If acoustic monitoring is being conducted for that pile, a received SPL may be estimated, or the received level may be estimated on the basis of past or subsequent acoustic monitoring. It may then be determined whether the animal was exposed to sound levels constituting incidental harassment in post-processing of observational and acoustic data, and a precise accounting of observed incidences of harassment created. Therefore, although the predicted distances to behavioral harassment thresholds are useful for estimating incidental harassment for purposes of authorizing levels of incidental take, actual take may be determined in part through the use of empirical data.

Acoustic measurements will continue during the fifth year of project activity and zones would be adjusted as indicated by empirical data. Please see the Navy's Acoustic and Marine Species Monitoring Plan (Monitoring Plan; available at *www.nmfs.noaa.gov/pr/permits/incidental/construction.htm*) for full details.

Monitoring Protocols—Monitoring would be conducted before, during, and after pile driving activities. In addition, observers shall record all incidents of marine mammal occurrence, regardless of distance from activity, and shall document any behavioral reactions in concert with distance from piles being driven. Observations made outside the shutdown zone will not result in shutdown; that pile segment would be completed without cessation, unless the animal approaches or enters the shutdown zone, at which point all pile driving activities would be halted. Monitoring will take place from fifteen minutes prior to initiation through thirty minutes post-completion of pile driving activities. Pile driving activities include the time to remove a single pile or series of piles, as long as the time elapsed between uses of the pile driving equipment is no more than thirty minutes. Please see the Monitoring Plan for full details of the monitoring protocols.

The following additional measures apply to visual monitoring:

(1) Monitoring will be conducted by qualified observers, who will be placed at the best vantage point(s) practicable (as defined in the Monitoring Plan) to monitor for marine mammals and implement shutdown/delay procedures when applicable by calling for the shutdown to the hammer operator. Qualified observers are trained biologists, with the following minimum qualifications:

(a) Visual acuity in both eyes (correction is permissible) sufficient for discernment of moving targets at the water's surface with ability to estimate target size and distance; use of binoculars may be necessary to correctly identify the target;

(b) Ability to conduct field observations and collect data according to assigned protocols;

(c) Experience or training in the field identification of marine mammals, including the identification of behaviors;

(d) Sufficient training, orientation, or experience with the construction operation to provide for personal safety during observations;

(e) Writing skills sufficient to prepare a report of observations including but not limited to the number and species of marine mammals observed; dates and times when in-water construction activities were conducted; dates and times when in-water construction activities were suspended to avoid potential incidental injury from construction sound of marine mammals observed within a defined shutdown zone; and marine mammal behavior; and

(f) Ability to communicate orally, by radio or in person, with project personnel to provide real-time information on marine mammals observed in the area as necessary.

(2) Prior to the start of pile driving activity, the shutdown zone will be monitored for fifteen minutes to ensure that it is clear of marine mammals. Pile driving will only commence once observers have declared the shutdown zone clear of marine mammals; animals will be allowed to remain in the shutdown zone (*i.e.,* must leave of their own volition) and their behavior will be monitored and documented. The shutdown zone may only be declared

clear, and pile driving started, when the entire shutdown zone is visible (*i.e.,* when not obscured by dark, rain, fog, *etc.*). In addition, if such conditions should arise during impact pile driving that is already underway, the activity would be halted.

(3) If a marine mammal approaches or enters the shutdown zone during the course of pile driving operations, activity will be halted and delayed until either the animal has voluntarily left and been visually confirmed beyond the shutdown zone or fifteen minutes have passed without re-detection of small cetaceans or pinnipeds and 30 minutes for gray whales. Monitoring will be conducted throughout the time required to drive a pile and for thirty minutes following the conclusion of pile driving.

Sound Attenuation Devices

The use of bubble curtains to reduce underwater sound from impact pile driving was considered prior to the start of the project but was determined to not be practicable. Use of a bubble curtain in a channel with substantial current may not be effective, as unconfined bubbles are likely to be swept away and confined curtain systems may be difficult to deploy effectively in high currents. Data gathered during monitoring of construction on the San Francisco-Oakland Bay Bridge indicated that no reduction in the overall linear sound level resulted from use of a bubble curtain in deep water with relatively strong current (Illingworth & Rodkin 2001). During project monitoring for pile driving associated with the Richmond-San Rafael Bridge, also in San Francisco Bay, it was observed that performance in moderate current was significantly reduced (Oestman *et al.,* 2009). Lucke *et al.* (2011) also note that the effectiveness of most currently used curtain designs may be compromised in stronger currents and greater water depths. We believe that conditions (relatively deep water and strong tidal currents of up to 3 knots (kn)) at the project site would disperse the bubbles and compromise the effectiveness of sound attenuation.

Timing Restrictions

In-order to avoid impacts to least tern populations when they are most likely to be foraging and nesting, in-water work will be concentrated from October 1–April 1 or, depending on circumstances, to April 30. However, this limitation is in accordance with agreements between the Navy and FWS, and is not a requirement of this proposed IHA. All in-water construction activities would occur only from 45 minutes after sunrise to 45 minutes before sunset.

Soft Start

The use of a soft start procedure is believed to provide additional protection to marine mammals by warning or providing a chance to leave the area prior to the hammer operating at full capacity, and typically involves a requirement to initiate sound from the hammer at reduced energy followed by a waiting period. This procedure is repeated two additional times. It is difficult to specify the reduction in energy for any given hammer because of variation across drivers and, for impact hammers, the actual number of strikes at reduced energy will vary because operating the hammer at less than full power results in ''bouncing'' of the hammer as it strikes the pile, resulting in multiple ''strikes.'' The project will utilize soft start techniques for impact pile driving. We require an initial set of three strikes from the impact hammer at reduced energy, followed by a thirty-second waiting period, then two subsequent three strike sets. Soft start will be required at the beginning of each day's impact pile driving work and at any time following a cessation of impact pile driving of thirty minutes or longer; the requirement to implement soft start for impact driving is independent of whether vibratory driving has occurred within the prior thirty minutes.

Based on our evaluation of the Navy's proposed measures, as well as any other potential measures that may be relevant to the specified activity, we have preliminarily determined that the proposed mitigation measures provide the means of effecting the least practicable impact on marine mammal species or stocks and their habitat, paying particular attention to rookeries, mating grounds, and areas of similar significance.

Proposed Monitoring and Reporting

In order to issue an IHA for an activity, section 101(a)(5)(D) of the MMPA states that NMFS must set forth ''requirements pertaining to the monitoring and reporting of such taking.'' The MMPA implementing regulations at 50 CFR 216.104(a)(13) indicate that requests for incidental take authorizations must include the suggested means of accomplishing the necessary monitoring and reporting that will result in increased knowledge of the species and of the level of taking or impacts on populations of marine mammals that are expected to be present in the proposed action area. Effective reporting is critical both to compliance as well as ensuring that the most value is obtained from the required monitoring.

Monitoring and reporting requirements prescribed by NMFS should contribute to improved understanding of one or more of the following:

- Occurrence of marine mammal species or stocks in the area in which take is anticipated (*e.g.,* presence, abundance, distribution, density).
- Nature, scope, or context of likely marine mammal exposure to potential stressors/impacts (individual or cumulative, acute or chronic), through better understanding of: (1) Action or environment (*e.g.,* source characterization, propagation, ambient noise); (2) Affected species (*e.g.,* life history, dive patterns); (3) Co-occurrence of marine mammal species with the action; or (4) Biological or behavioral context of exposure (*e.g.,* age, calving or feeding areas).
- Individual marine mammal responses (behavioral or physiological) to acoustic stressors (acute, chronic, or cumulative), other stressors, or impacts from multiple stressors.
- How anticipated responses to stressors impact either: (1) Long-term fitness and survival of an individual; or (2) Population, species, or stock.
- Effects on marine mammal habitat (*e.g.* marine mammal prey species, acoustic habitat, or other important physical components of marine mammal habitat).
- Mitigation and monitoring effectiveness.

Please see the Monitoring Plan (available at *www.nmfs.noaa.gov/pr/permits/incidental/construction.htm*) for full details of the requirements for monitoring and reporting. Notional monitoring locations (for biological and acoustic monitoring) are shown in Figures 3–1 and 3–2 of the Plan. The purpose of this Plan is to provide protocols for acoustic and marine mammal monitoring implemented during pile driving and removal activities. We have preliminarily determined this monitoring plan, which is summarized here and which largely follows the monitoring strategies required and successfully implemented under the previous IHAs, to be sufficient to meet the MMPA's monitoring and reporting requirements. The previous monitoring plan was modified to integrate adaptive changes to the monitoring methodologies as well as updates to the scheduled construction activities. Monitoring objectives are as follows:

- Monitor in-water construction activities, including the implementation of in-situ acoustic monitoring efforts to

continue to measure SPLs from in-water construction and demolition activities not previously monitored or validated during the previous IHAs. This would include collection of acoustic data for activities and pile types for which sufficient data has not previously been collected, including for diamond saw cutting of caissons and pile clipping of the concrete piles during fuel pier demolition. The Navy also plans to collect acoustic data for vibratory extraction and/or driving, impact driving, jetting pile extraction and pile dead-pull of the concrete piles at NMAWC.

- Monitor marine mammal occurrence and behavior during in-water construction activities to minimize marine mammal impacts and effectively document marine mammals occurring within ZOI boundaries.

Collection of ambient underwater sound measurements in the absence of project activities has been concluded, as a rigorous baseline dataset for the project area has been developed.

Acoustic Measurements

The primary purpose of acoustic monitoring is to empirically verify modeled injury and behavioral disturbance zones (defined at radial distances to NMFS-specified thresholds; see *Estimated Take by Incidental Harassment*). For non-pulsed sound, distances will continue to be evaluated for attenuation to the point at which sound becomes indistinguishable from background levels. Empirical acoustic monitoring data will be used to document transmission loss values determined from past measurements and to examine site-specific differences in SPL and affected ZOIs on an as needed basis.

Should monitoring results indicate it is appropriate to do so, marine mammal mitigation zones may be revised as necessary to encompass actual ZOIs. Acoustic monitoring will be conducted as specified in the approved Monitoring Plan. Please see Table 2–2 of the Plan for a list of equipment to be used during acoustic monitoring. Monitoring locations will be determined based on results of previous acoustic monitoring effort and the best professional judgment of acoustic technicians.

For activities such as demolition of the old fuel pier and temporary mooring dolphin, the Navy will continue to collect in situ acoustic data to validate source levels and ZOIs. Environmental data would be collected including but not limited to: Wind speed and direction, air temperature, humidity, surface water temperature, water depth, wave height, weather conditions and other factors that could contribute to influencing the airborne and underwater sound levels (*e.g.,* aircraft, boats). Full details of acoustic monitoring requirements may be found in section 4.2 of the Navy's Monitoring Plan.

Visual Marine Mammal Observations

The Navy will collect sighting data and behavioral responses to construction for marine mammal species observed in the region of activity during the period of activity. All observers will be trained in marine mammal identification and behaviors and are required to have no other construction-related tasks while conducting monitoring. The Navy will monitor the shutdown zone and disturbance zone before, during, and after pile driving as described under *Proposed Mitigation* and in the Monitoring Plan, with observers located at the best practicable vantage points. Notional monitoring locations are shown in Figures 3–3 and 3–4 of the Navy's Plan. Please see that plan, available at *www.nmfs.noaa.gov/pr/permits/incidental/construction.htm,* for full details of the required marine mammal monitoring. Section 3.2 of the Plan and Section 13 of the Navy's application offer more detail regarding monitoring protocols. Based on our requirements, the Navy would implement the following procedures for pile driving:

- MMOs would be located at the best vantage point(s) in order to properly see the entire shutdown zone and as much of the disturbance zone as possible.
- During all observation periods, observers will use binoculars and the naked eye to search continuously for marine mammals.
- If the shutdown zones are obscured by fog or poor lighting conditions, pile driving at that location will not be initiated until that zone is visible. Should such conditions arise while impact driving is underway, the activity would be halted.
- The shutdown and disturbance zones around the pile will be monitored for the presence of marine mammals before, during, and after any pile driving or removal activity.

One MMO will be placed in the most effective position near the active construction/demolition platform in order to observe the respective shutdown zones for vibratory and impact pile driving or for applicable demolition activities. Monitoring would be primarily dedicated to observing the shutdown zone; however, MMOs would record all marine mammal sightings beyond these distances provided it did not interfere with their effectiveness at carrying out the shutdown procedures. Additional land, pier, or vessel-based MMOs will be positioned to monitor the shutdown zones and the buffer zones, as notionally indicated in Figures 3–3 and 3–4 of the Navy's application.

For all pile driving and applicable demolition activities, a minimum of one observer shall monitor the shutdown zones. However, any action requiring the impact or vibratory hammer will necessitate two MMOs. For impact and vibratory pile driving of 16-in concrete piles, two observers shall be positioned for optimal monitoring of the surrounding waters.

The MMOs will record all visible marine mammal sightings. Confirmed takes will be registered once the sightings data has been overlaid with the isopleths identified in Table 5 and visualized in Figures 6–2, 6–3, and 6–4 of the Navy's application, or based on refined acoustic data, if amendments to the ZOIs are needed. Acousticians on duty may be noting SPLs in real-time, but, to avoid biasing the observations, will not communicate that information directly to the MMOs. These platforms may move closer to, or farther from, the source depending on whether received SPLs are less than or greater than the regulatory threshold values. All MMOs will be in radio communication with each other so that the MMOs will know when to anticipate incoming marine mammal species and when they are tracking the same animals observed elsewhere.

If any species for which take is not authorized is observed by a MMO during applicable construction or demolition activities, all construction will be stopped immediately. Pile driving will commence if the animal has not been seen inside the Level B ZOI for at least one hour of observation. If the animal is resighted again, pile driving will be stopped and a boat-based MMO (if available) will follow the animal until it has left the Level B ZOI. If the animal is resighted again, pile driving will be stopped and a boat-based MMO (if available) will follow the animal until it has left the Level B ZOI.

Individuals implementing the monitoring protocol will assess its effectiveness using an adaptive approach. Monitoring biologists will use their best professional judgment throughout implementation and seek improvements to these methods when deemed appropriate. Any modifications to protocol will be coordinated between NMFS and the Navy.

Data Collection

We require that observers use approved data forms. Among other

pieces of information, the Navy will record detailed information about any implementation of shutdowns, including the distance of animals to the pile and description of specific actions that ensued and resulting behavior of the animal, if any. In addition, the Navy will attempt to distinguish between the number of individual animals taken and the number of incidents of take. We require that, at a minimum, the following information be collected on the sighting forms:

- Date and time that monitored activity begins or ends;
- Construction activities occurring during each observation period;
- Weather parameters (*e.g.,* percent cover, visibility);
- Water conditions (*e.g.,* sea state, tide state);
- Species, numbers, and, if possible, sex and age class of marine mammals;
- Description of any observable marine mammal behavior patterns, including bearing and direction of travel and distance from pile driving activity, and if possible, the correlation to measured SPLs;
- Distance from pile driving activities to marine mammals and distance from the marine mammals to the observation point;
- Description of implementation of mitigation measures (*e.g.,* shutdown or delay);
- Locations of all marine mammal observations; and
- Other human activity in the area.

In addition, photographs would be taken of any gray whales observed. These photographs would be submitted to NMFS' West Coast Regional Office for comparison with photo-identification catalogs to determine whether the whale is a member of the WNP population.

Reporting

A draft report would be submitted to NMFS within 45 calendar days of the completion of marine mammal monitoring, or 60 days prior to the issuance of any subsequent IHA for this project, whichever comes first. The report will include marine mammal observations pre-activity, during-activity, and post-activity during pile driving days, and will also provide descriptions of any behavioral responses to construction activities by marine mammals and a complete description of all mitigation shutdowns and the results of those actions. A final report would be prepared and submitted within thirty days following resolution of comments on the draft report. Required contents of the monitoring reports are described in more detail in the Navy's Acoustic and Marine Species Monitoring Plan.

Monitoring Results From Previously Authorized Activities

The Navy complied with the mitigation and monitoring required under the previous authorizations for this project. Acoustic and marine mammal monitoring was implemented as required, with marine mammal monitoring occurring before, during, and after each pile driving event. During the course of Year 4 activities, the Navy did not exceed the take levels authorized under the IHA (please see the Navy's monitoring report for more details and below for further discussion).

The general objectives of the monitoring plan were similar to those described above for the Year 5 monitoring plan. For acoustic monitoring, the primary goal was to continue to collect in situ data towards validation of the acoustic ZOIs defined based on previous data collection efforts and using the transmission loss modeling effort conducted prior to the start of the project, and to continue collection of data on background noise conditions in San Diego Bay.

Acoustic Monitoring Results—For a full description of acoustic monitoring methodology, please see section 2.3 of the Navy's monitoring report, including Figure 2–3 for representative monitoring locations. Results from Years 1–4 are displayed in Table 11. Please see our notices of proposed IHAs for the Years 2, 3, and 4 IHAs (79 FR 53026, September 5, 2014; 80 FR 53115, September 2, 2015; and 81 FR 66628, September 28, 2016) or the Navy's Year 1 and 2 monitoring reports for more detailed description of monitoring accomplished during the first two years of the project.

For acoustic monitoring associated with impact pile driving, continuous hydroacoustic monitoring systems were positioned at source (10 m from the pile) and opportunistically at predicted 160-dB Level B ZOIs. The far-field data collections were conducted at multiple locations during impact driving of 16-in concrete-filled poly piles and 24 x 30-in concrete fender piles, *i.e.,* approximately 20 to 550 m from source. Hydrophones were deployed from the dock, barge, or moored vessel at half the water depth. The SPLs for driving of 30-in steel pipe piles were measured intermittently and archived (but not reported) because associated SPLs for the size, type, and location of the piles were previously validated. Source SPLs were recorded and analyzed for a minimum of five piles for each of the concrete pile types. Additional measurements were archived.

SPLs of pile driving and demolition activities conducted during Year 2 fell within expected levels but varied spatially relative to the existing fuel pier structure and maximum source levels for individual piles (Table 11). For both vibratory and impact pile driving methods, results from the IPP (Year 1) and 2014/2015 production pile driving (Year 2) showed that transmission loss for piles driven in shallow water inside of the existing fuel pier was greater than piles driven in deep water outside of the existing pier. Differences in depth, sediment type, and existing in-water pier/wharf structures likely accounted for variations in transmission loss and measured differences in SPLs recorded at the shutdown and far-field locations for shallow versus deep piles of the same type and size. SPLs documented during vibratory and impact pile driving of shallow and deep steel pipe piles of the same size displayed notable differences in SPLs at shutdown range and to a lesser extent at source.

Measurements of impact driving of concrete piles conducted during Year 3 produced greater than expected SPLs at source. Differences in the subsurface conditions may account for the discrepancy, as a hardened layer is found at approximately 20–40 m below the mudline. SPLs documented during driving of 16-in piles generally displayed relatively low sound source levels during initial driving then appreciable increases observed once the piles interacted with this layer. Measurements from driving of the square concrete piles showed greatest sound source levels during initial impact pile driving, which then decreased once the piles transitioned through the hardened layer. While source SPLs were observed to be greater than expected for both pile types, attenuation was also greater. Despite greater than expected source levels, the measured isopleth distances were similar to modeled predictions. Far-field impact pile driving results varied substantially between piles and locations for the various pile sizes, types, and locations. Both pile types were driven adjacent to the new fuel pier and source SPLs were subject to a wide variety of boundary conditions from recently driven piles and associated pier infrastructure. Further detail and discussion is provided in the Navy's report.

During Year 4, measurements were conducted for pile clipping, caisson cutting, pile jetting, and airborne vibratory and impact driving. The average SPLs for pile clipping at source ranged from 138.0 to 144.6 dB rms, with maximum SPLs at source ranging from

156.1 to 165.3 dB rms (see Table 6–3 of the Navy's monitoring report). Measurements were conducted on eight piles and took one to three minutes to cut.

Caisson demolition was conducted on 18 84-in concrete-filled caissons, with an average duration of approximately 6 hours per caisson. Underwater acoustic data was collected for seven caissons using the vibratory setting. For some of the recordings, there were two caissons being cut simultaneously and the acousticians captured the SPLs for comparison between a single cutter versus two cutters. If two cutters were running, the distance measured was from the closest caisson to the location. Average SPLs at source for a single cutter were 136.1 and 141.4 dB rms. Maximum SPLs at source for a single cutter were 140.9 and 146.5 dB rms. Average SPLs at source for two cutters running simultaneously were 146.5 and 149.0 dB rms. Maximum SPLs at source for two cutters running simultaneously were 149.0 and 155.6 dB rms. On average, there was a 10 dB difference between a single cutter and two at source. Far-field recordings for a single cutter were collected at far-field locations ranging from 20 to 430 m (66 to 1,411 ft), with documented maximum SPL values from 136.6 to 145.5 dB rms. Far-field recordings for two cutters were also collected at far-field locations ranging from 85 to 810 m (279 to 2,657 ft), with documented maximum SPL values from 133.2 to 146.8 dB rms.

SPLs of pile installation activities for the 24 x 30 concrete piles had not been previously documented. The only jetting data collected during the Project was at NMAWC during the removal of 12-inch and 16-inch concrete piles. A total of sixteen 24 x 30 concrete non-structural fender piles were driven using two techniques: (1) Method 1 (M1) utilized a custom-made spud jet with four nozzles welded to the tip that used a high-pressure water system (900 gallons per minute with a maximum pounds per square inch [psi] of 300), to make the initial break through the bay point formation sediment layer; and (2) Method 2 (M2) used the 24 x 30 pile, outfitted with two pipes inside the full length of the pile, which then used a high-pressure water system (maximum psi of 300) to remove sediment and place the pile. Pile jetting averaged 24.5 minutes per pile and acoustic recordings were collected for the entire duration. Collection of underwater acoustic data were completed on six piles using the vibratory setting. For M1, the average sound pressure levels (SPL) at source ranged from 152.6 dB rms to 155.1 dB rms, and maximum SPLs at source ranged from 156.5 dB rms to 159.9 dB rms. For M2, the average SPL at source ranged from 133.0 dB to 149.8 dB and maximum SPLs at source ranged from 137.1 dB to 153.2 dB rms. A vessel based drift method was used to obtain far-field recordings during M1 and M2 jetting techniques; the vessel was initially positioned at the closest feasible distance to source, and then the allowed to drift on the natural tidal current until near ambient sound pressure levels were obtained. The SPLs at far-field for the first drift during jetting M1 reached near ambient at 165 m (541 ft) from pile with an SPL of 128.0 dB. The SPLs at far-field for the first drift during pile jetting M2 reached near ambient at 80 m (262 ft) from pile with an SPL of 127.6 dB. Recordings during the vessel drifts showed that jetting reached near ambient levels for both methods between 80 m (262 ft) and 165 m (541 ft; M1 and M2, respectively).

Airborne sound levels were recorded during vibratory pile driving on fourteen 30-inch steel piles. The maximum recorded airborne dB rms values at source was 106.3 dB re 20 µPa, and average values ranged from 96.0 to 102.7 dB re 20 µPa. Airborne sound levels were recorded during impact pile driving on sixteen 30-inch steel piles. The maximum recorded airborne dB values at source was 118.5 dB re 20 µPa, and average values ranged from 105.8 to 112.5 dB re 20 µPa. Further detail and discussion is provided in the Navy's report.

TABLE 11—ACOUSTIC MONITORING RESULTS FOR YEAR 4

Location	Activity	Pile type	Number of piles measured	Average underwater SPL at 10 m (dB rms)	Average airborne SPL (LZF_{max}) [1]
Fuel Pier (Year 4)	Pile Clipping	24-in square concrete pile	4	141	
	Caisson Demolition (1 cutter)	84-in caisson	10	136	
	Caisson Demolition (2 cutters).	84-in caisson	8	138	
	Vibratory	30-in steel (at source)	7		100
	Vibratory	30-in steel (far field)	7		86
	Impact	30-in steel (at source)	9		110
	Impact	30-in steel (far field)	7		88
NMAWC (Year 4)	Pile Jetting	24x30	10	147	

[1] Measured from Source (15.2 m) and Far-field Distances for 30-inch Steel Piles.

Marine Mammal Monitoring Results—Marine mammal monitoring was conducted as required under the IHA and as described in the Year 4 monitoring plan and in our **Federal Register** notice of proposed authorization associated with the Year 4 IHA. For a full description of monitoring methodology, please see section 2 of the Navy's monitoring report, including Figure 2–1, 2–2, and 2–7 for representative monitoring locations and Figures 2–2 through 2–5 for monitoring zones. Monitoring protocols were managed adaptively during the course of the fourth-year IHA. Multiple shutdowns were implemented due to marine mammals being observed within buffered shutdown zones, but no animals were observed within actual predicted Level A harassment zones while pile driving was occurring (one harbor seal was seen within the Level A ZOI after a shutdown of construction had been implemented).

Monitoring results are presented in Table 12. The Navy recorded all observations of marine mammals, including pre- and post-construction monitoring efforts. Animals observed during these periods or that were determined to be outside relevant ZOIs were not considered to represent incidents of take. Please see Figures 3–11, 3–12, 3–22, 3–23, 3–30, and 3–31 of the Navy's Monitoring Report for locations of observations and incidents of take relative to the project sites. Take authorization for the second-year authorization was informed by an assumption that 115 days of in-water construction would occur, whereas only

fifty total days actually occurred. However, the actual observed rates per day were in all cases lower than what was assumed. Therefore, we expect that the Navy would not have exceeded the take allowances even if the full 115 days had been reached.

There were considerably fewer individuals and sightings during the Year 3 IHA when compared to the same months during the Year 2 IHA, and only three species were observed. This may be due to environmental fluctuations as part of the on-going El Niño event. Water temperatures during Year 3 were warmer than during the same months during Year 2. Although the temperatures were still higher than the average water temperatures for the region prior to the current El Niño event, it shows that the event may have been dissipating. In addition, California sea lion strandings decreased. No evidently significant behavioral changes were reported.

Similar to Year 3, there were considerably fewer individuals and sightings during the Year 4 IHA when compared to the same months during the Year 2 IHA, and only four species were observed. This may be due to environmental fluctuations as part of the on-going El Niño event. Water temperatures during Year 4 were slightly warmer than during the same months during Year 2. Although the temperatures were still higher than the average water temperatures for the region prior to the current El Niño event, it shows that the event may have been dissipating. In addition, California sea lion strandings decreased, but may be returning to numbers more commonly observed. No evidently significant behavioral changes were reported.

TABLE 12—MARINE MAMMAL MONITORING RESULTS FOR YEAR 4

Species	Total sightings	Total individuals	Observed incidents of Level B take	Extrapolated incidents of Level B take [1]	Total estimated Level B take
California sea lion	717	2,037	156	1,835	1,991
Harbor seal	87	102	21	57	78
Bottlenose dolphin	18	45	4	144	148
Gray whale	1	1	0	13	13

[1] Assumed density and unmonitored area of assumed Level B ZOI used with actual pile driving time to generate assumed take for unmonitored areas.

Negligible Impact Analysis and Determination

NMFS has defined negligible impact in 50 CFR 216.103 as an impact resulting from the specified activity that cannot be reasonably expected to, and is not reasonably likely to, adversely affect the species or stock through effects on annual rates of recruitment or survival. A negligible impact finding is based on the lack of likely adverse effects on annual rates of recruitment or survival (*i.e.,* population-level effects). An estimate of the number of takes alone is not enough information on which to base an impact determination. In addition to considering estimates of the number of marine mammals that might be ''taken'' through harassment, NMFS considers other factors, such as the likely nature of any responses (*e.g.,* intensity, duration), the context of any responses (*e.g.,* critical reproductive time or location, migration), as well as effects on habitat, and the likely effectiveness of the mitigation. We also assess the number, intensity, and context of estimated takes by evaluating this information relative to population status. Consistent with the 1989 preamble for NMFS's implementing regulations (54 FR 40338; September 29, 1989), the impacts from other past and ongoing anthropogenic activities are incorporated into this analysis via their impacts on the environmental baseline (*e.g.,* as reflected in the regulatory status of the species, population size and growth rate where known, ongoing sources of human-caused mortality, or ambient noise levels).

Construction and demolition activities associated with the pier replacement project, as outlined previously, have the potential to disturb or displace marine mammals. Specifically, the specified activities may result in take, in the form of Level B harassment (behavioral disturbance) only, from underwater sounds generated from pile driving. Potential takes could occur if individuals of these species are present in the ensonified zone when pile driving or removal is happening.

No injury, serious injury, or mortality is anticipated given the nature of the activity and measures designed to minimize the possibility of injury to marine mammals. The potential for these outcomes is minimized through the construction method and the implementation of the planned mitigation measures. Impact pile driving produces short, sharp pulses with higher peak levels and much sharper rise time to reach those peaks. When impact driving is necessary, required measures (implementation of buffered shutdown zones) significantly reduce any possibility of injury. Given sufficient ''notice'' through use of soft start (for impact driving), marine mammals are expected to move away from a sound source that is annoying prior to its becoming potentially injurious. The likelihood that marine mammal detection ability by trained observers is high under the environmental conditions described for San Diego Bay (approaching 100 percent detection rate, as described by trained biologists conducting site-specific surveys) further enables the implementation of shutdowns to avoid injury, serious injury, or mortality.

Effects on individuals that are taken by Level B harassment, on the basis of reports in the literature as well as monitoring from past years of this project and other similar activities, will likely be limited to reactions such as increased swimming speeds, increased surfacing time, or decreased foraging (if such activity were occurring) (*e.g.,* Thorson and Reyff, 2006; HDR, 2012; Lerma, 2014). Most likely, individuals will simply move away from the sound source and be temporarily displaced from the areas of pile driving, although even this reaction has been observed primarily only in association with impact pile driving. In response to vibratory driving, pinnipeds (which may become somewhat habituated to human activity in industrial or urban waterways) have been observed to orient towards and sometimes move towards the sound. The pile driving activities analyzed here are similar to, or less impactful than, numerous other construction activities conducted in San Francisco Bay and in the Puget Sound region, which have taken place with no

reported injuries or mortality to marine mammals, and no known long-term adverse consequences from behavioral harassment. Repeated exposures of individuals to levels of sound that may cause Level B harassment are unlikely to result in hearing impairment or to significantly disrupt foraging behavior. Thus, even repeated Level B harassment of some small subset of the overall stock is unlikely to result in any significant realized decrease in fitness for the affected individuals, and thus would not result in any adverse impact to the stock as a whole. Level B harassment will be reduced to the level of least practicable impact through use of mitigation measures described herein and, if sound produced by project activities is sufficiently disturbing, animals are likely to simply avoid the project area while the activity is occurring.

In summary and as described above, the following factors primarily support our preliminary determination that the impacts resulting from this activity are not expected to adversely affect the species or stock through effects on annual rates of recruitment or survival:

- No mortality is anticipated or authorized;
- The anticipated incidents of Level B harassment consist of, at worst, temporary modifications in behavior;
- The absence of any significant habitat within the project area, including rookeries, significant haul-outs, or known areas or features of special significance for foraging or reproduction; and
- The presumed efficacy of the proposed mitigation measures in reducing the effects of the specified activity to the level of least practicable impact.

Based on the analysis contained herein of the likely effects of the specified activity on marine mammals and their habitat, and taking into consideration the implementation of the proposed monitoring and mitigation measures, NMFS preliminarily finds that the total marine mammal take from the proposed activity will have a negligible impact on all affected marine mammal species or stocks.

Small Numbers

As noted above, only small numbers of incidental take may be authorized under Section 101(a)(5)(D) of the MMPA for specified activities other than military readiness activities. The MMPA does not define small numbers and so, in practice, where estimated numbers are available, NMFS compares the number of individuals taken to the most appropriate estimation of abundance of the relevant species or stock in our determination of whether an authorization is limited to small numbers of marine mammals. Additionally, other qualitative factors may be considered in the analysis, such as the temporal or spatial scale of the activities.

The number of incidents of take proposed for authorization for these stocks, with the exception of the coastal bottlenose dolphin (see below), would be considered small relative to the relevant stocks or populations (see Table 9) even if each estimated taking occurred to a new individual. This is an extremely unlikely scenario as, for pinnipeds occurring at the NBPL waterfront, there will almost certainly be some overlap in individuals present day-to-day and in general, there is likely to be some overlap in individuals present day-to-day for animals in estuarine/inland waters.

The proposed numbers of authorized take for bottlenose dolphins are higher relative to the total stock abundance estimate and would not represent small numbers if a significant portion of the take was for a new individual. However, these numbers represent the estimated incidents of take, not the number of individuals taken. That is, it is likely that a relatively small subset of California coastal bottlenose dolphins would be incidentally harassed by project activities. California coastal bottlenose dolphins range from San Francisco Bay to San Diego (and south into Mexico) and the specified activity would be stationary within an enclosed water body that is not recognized as an area of any special significance for coastal bottlenose dolphins (and is therefore not an area of dolphin aggregation, as evident in Navy observational records). We therefore believe that the estimated numbers of takes, were they to occur, likely represent repeated exposures of a much smaller number of bottlenose dolphins and that, based on the limited region of exposure in comparison with the known distribution of the coastal bottlenose dolphin, these estimated incidents of take represent small numbers of bottlenose dolphins.

Based on the analysis contained herein of the proposed activity (including the proposed mitigation and monitoring measures) and the anticipated take of marine mammals, NMFS preliminarily finds that small numbers of marine mammals will be taken relative to the population size of the affected species or stocks.

Impact on Availability of Affected Species for Taking for Subsistence Uses

There are no relevant subsistence uses of the affected marine mammal stocks or species implicated by this action. Therefore, NMFS has preliminarily determined that the total taking of affected species or stocks would not have an unmitigable adverse impact on the availability of such species or stocks for taking for subsistence purposes.

Endangered Species Act (ESA)

Section 7(a)(2) of the Endangered Species Act of 1973 (ESA: 16 U.S.C. 1531 *et seq.*) requires that each Federal agency insure that any action it authorizes, funds, or carries out is not likely to jeopardize the continued existence of any endangered or threatened species or result in the destruction or adverse modification of designated critical habitat. To ensure ESA compliance for the issuance of IHAs, NMFS consults internally, in this case with the ESA Interagency Cooperation Division, whenever we propose to authorize take for endangered or threatened species.

The Navy initiated informal consultation under section 7 of the ESA with NMFS Southwest Regional Office (now West Coast Regional Office) on March 5, 2013. NMFS concluded on May 16, 2013, that the proposed action may affect, but is not likely to adversely affect, WNP gray whales. The Navy has not requested authorization of the incidental take of WNP gray whales and no such authorization is proposed, and there are no other ESA-listed marine mammals found in the action area. Therefore, no consultation under the ESA is required.

Proposed Authorization

As a result of these preliminary determinations, NMFS proposes to issue an IHA to the Navy for conducting the described pier replacement activities in San Diego Bay, for a period of one year from the date of issuance, provided the previously mentioned mitigation, monitoring, and reporting requirements are incorporated. This section contains a draft of the IHA itself. The wording contained in this section is proposed for inclusion in the IHA (if issued).

1. This Incidental Harassment Authorization (IHA) is valid from October 8, 2017, through October 7, 2018.

2. This IHA is valid only for pile driving and removal activities associated with the Fuel Pier Replacement Project at the Naval Station Point Loma in San Diego Bay, California.

3. General Conditions

(a) A copy of this IHA must be in the possession of the Navy, its designees, and work crew personnel operating under the authority of this IHA.

(b) The species authorized for taking are the harbor seal (*Phoca vitulina richardii*), California sea lion (*Zalophus californianus*), bottlenose dolphin (*Tursiops truncatus truncatus*), common dolphin (*Delphinus delphis*), northern elephant seal (*Mirounga angustirostris*), Pacific white-sided dolphin (*Lagenorhynchus obliquidens*), Risso's dolphin (*Grampus griseus*), and gray whale (*Eschrichtius robustus*).

(c) The taking, by Level B harassment only, is limited to the species listed in condition 3(b). See Table 1 for numbers of take authorized.

TABLE 1—AUTHORIZED TAKE NUMBERS, BY SPECIES

Species	Authorized take
California sea lion	8,971
Harbor seal	281
Northern elephant seal	43
California coastal bottlenose dolphin	704
Common dolphin	861
Pacific white-sided dolphin	28
Risso's dolphin	114
Gray whale	10

(d) The taking by injury (Level A harassment), serious injury, or death of any of the species listed in condition 3(b) of the Authorization or any taking of any other species of marine mammal is prohibited and may result in the modification, suspension, or revocation of this IHA.

(e) The Navy shall conduct briefings between construction supervisors and crews, marine mammal monitoring team, acoustic monitoring team, and Navy staff prior to the start of all pile driving activity, and when new personnel join the work, in order to explain responsibilities, communication procedures, marine mammal monitoring protocol, and operational procedures.

4. Mitigation Measures

The holder of this Authorization is required to implement the following mitigation measures:

(a) For all pile driving, the Navy shall implement a minimum shutdown zone of 10 m radius around the pile. If a marine mammal comes within or approaches the shutdown zone, such operations shall cease. See Table 2 for minimum radial distances required for shutdown zones.

TABLE 2—RADIAL DISTANCE TO SHUTDOWN AND DISTURBANCE ZONES ASSOCIATED WITH RELEVANT THRESHOLDS, INCLUDING BUFFERS

Activity	Monitored distances to thresholds (meters)							
	Underwater						Airborne	
	Level A				Level B		Level B	
	LF [1]	MF [1]	PW [1]	OW [1]	160 dB	120 dB [2]	100 dB	90 dB
Old Fuel Pier and Temporary Mooring Dolphin Demolition								
66-inch and 84-inch caissons (Diamond saw cutting)	10				N/A	631	N/A [3]	
Concrete piles (Pile clipping)	10				N/A	2,511		
30-inch steel piles (Plasma torch cutting)	10				N/A			
NMAWC Construction and Demolition								
16-inch concrete piles (Vibratory extraction/ driving)	20 [4]		10		N/A	1,848	42	149
16-inch concrete piles (Impact driving)	100 [5]		60 [6]		270	N/A		
16-inch concrete piles (Jetting pile extraction)	10				N/A	1,165	N/A [3]	
16-inch concrete piles (Pile dead-pull)	10				N/A			

[1] LF = Low-frequency cetaceans; MF = Mid-frequency cetaceans; PW = Phocid pinnipeds; OW = Otariid pinnipeds. The high-frequency cetacean hearing group (HF) is omitted, because no species in the hearing group occur in, or around, Project area.
[2] Mean ambient sound levels in San Diego Bay are approximately 128 dB rms (NAVFAC SW 2015), and all 120 dB Level B ZOIs are based on the ambient value.
[3] Airborne noise levels did not exceed regulatory thresholds during previous IHAs. No airborne monitoring will take place for diamond saw cutting of caissons, plasma torch cutting of temporary mooring dolphin 30-inch steel piles, jetting or dead-pull extraction of concrete piles.
[4] Includes buffer of calculated Level A threshold out to 20 m (65.6 ft).
[5] Includes buffer of calculated Level A threshold out to 100 m (328 ft).
[6] Includes buffer of calculated Level A threshold out to 60 m (197 ft).

(b) The Navy shall shutdown activity as appropriate upon observation of any species for which take is not authorized. Activity shall not be resumed until those species have been observed to leave the relevant zone or until one hour has elapsed.

(c) The Navy shall deploy marine mammal observers as described below and as indicated in the Acoustic and Marine Species Monitoring Plan (Monitoring Plan; attached).

i. For all pile driving and applicable demolition activities, a minimum of one observer shall monitor the shutdown zones. However, any action requiring the impact or vibratory hammer will necessitate two MMOs.

ii. For impact and vibratory pile driving of 16-in concrete piles, two observers shall be positioned for optimal monitoring of the surrounding waters.

iii. These observers shall record all observations of marine mammals, regardless of distance from the pile being driven, as well as behavior and potential behavioral reactions of the animals.

iv. All observers shall be equipped for communication of marine mammal observations amongst themselves and to other relevant personnel (*e.g.,* those necessary to effect activity delay or shutdown).

(d) Monitoring shall take place from fifteen minutes prior to initiation of pile driving activity through thirty minutes post-completion of pile driving activity. Pre-activity monitoring shall be conducted for fifteen minutes to ensure that the shutdown zone is clear of marine mammals, and pile driving may commence when observers have declared the shutdown zone clear of marine mammals. In the event of a delay or shutdown of activity resulting from marine mammals in the shutdown zone, animals shall be allowed to remain in the shutdown zone (*i.e.,* must leave of their own volition) and their behavior shall be monitored and documented. Monitoring shall occur throughout the time required to drive a pile. The shutdown zone must be determined to be clear during periods of good visibility (*i.e.,* the entire shutdown zone and surrounding waters must be visible to the naked eye).

(e) If a marine mammal approaches or enters the shutdown zone, all pile driving activities at that location shall be halted. If pile driving is halted or delayed due to the presence of a marine mammal, the activity may not commence or resume until either the animal has voluntarily left and been visually confirmed beyond the shutdown zone or 30 minutes have passed without re-detection of gray whales or 15 minutes for all other animals.

(f) Monitoring shall be conducted by qualified observers, as described in the Monitoring Plan. Trained observers shall be placed from the best vantage point(s) practicable to monitor for marine mammals and implement shutdown or delay procedures when applicable through communication with the equipment operator.

(g) The Navy shall use soft start techniques recommended by NMFS for impact pile driving. Soft start for impact drivers requires contractors to provide an initial set of strikes at reduced energy, followed by a thirty-second waiting period, then two subsequent reduced energy strike sets. Soft start shall be implemented at the start of each day's impact pile driving and at any time following cessation of impact pile driving for a period of 30 minutes or longer.

(h) Pile driving shall only be conducted during daylight hours.

5. Monitoring

The holder of this Authorization is required to conduct marine mammal monitoring during pile driving activity. Marine mammal monitoring and reporting shall be conducted in accordance with the Monitoring Plan.

(a) The Navy shall collect sighting data and behavioral responses to pile driving for marine mammal species observed in the region of activity during the period of activity. All observers shall be trained in marine mammal identification and behaviors, and shall have no other construction-related tasks while conducting monitoring.

(b) For all marine mammal monitoring, the information shall be recorded as described in the Monitoring Plan.

(c) The Navy shall conduct acoustic monitoring for representative scenarios of pile driving activity, as described in the Monitoring Plan.

6. Reporting

The holder of this Authorization is required to:

(a) Submit a draft report on all monitoring conducted under the IHA within 45 calendar days of the completion of marine mammal and acoustic monitoring, or 60 days prior to the issuance of any subsequent IHA for this project, whichever comes first. A final report shall be prepared and submitted within thirty days following resolution of comments on the draft report from NMFS. This report must contain the informational elements described in the Monitoring Plan, at minimum (see attached), and shall also include:

i. Detailed information about any implementation of shutdowns, including the distance of animals to the pile and description of specific actions that ensued and resulting behavior of the animal, if any.

ii. Description of attempts to distinguish between the number of individual animals taken and the number of incidences of take, such as ability to track groups or individuals.

iii. Results of acoustic monitoring, including the information described in in the Monitoring Plan.

(b) Reporting injured or dead marine mammals:

i. In the unanticipated event that the specified activity clearly causes the take of a marine mammal in a manner prohibited by this IHA, such as an injury (Level A harassment), serious injury, or mortality, Navy shall immediately cease the specified activities and report the incident to the Office of Protected Resources, NMFS, and the West Coast Regional Stranding Coordinator, NMFS. The report must include the following information:

A. Time and date of the incident;

B. Description of the incident;

C. Environmental conditions (*e.g.,* wind speed and direction, Beaufort sea state, cloud cover, and visibility);

D. Description of all marine mammal observations in the 24 hours preceding the incident;

E. Species identification or description of the animal(s) involved;

F. Fate of the animal(s); and

G. Photographs or video footage of the animal(s).

Activities shall not resume until NMFS is able to review the circumstances of the prohibited take. NMFS will work with Navy to determine what measures are necessary to minimize the likelihood of further prohibited take and ensure MMPA compliance. Navy may not resume their activities until notified by NMFS.

i. In the event that Navy discovers an injured or dead marine mammal, and the lead observer determines that the cause of the injury or death is unknown and the death is relatively recent (*e.g.,* in less than a moderate state of decomposition), Navy shall immediately report the incident to the Office of Protected Resources, NMFS, and the West Coast Regional Stranding Coordinator, NMFS.

The report must include the same information identified in 6(b)(i) of this IHA. Activities may continue while NMFS reviews the circumstances of the incident. NMFS will work with Navy to determine whether additional mitigation measures or modifications to the activities are appropriate.

ii. In the event that Navy discovers an injured or dead marine mammal, and the lead observer determines that the injury or death is not associated with or related to the activities authorized in the IHA (*e.g.,* previously wounded animal, carcass with moderate to advanced decomposition, scavenger damage), Navy shall report the incident to the Office of Protected Resources, NMFS, and the West Coast Regional Stranding Coordinator, NMFS, within 24 hours of the discovery. Navy shall provide photographs or video footage or other documentation of the stranded animal sighting to NMFS.

7. This Authorization may be modified, suspended or withdrawn if the holder fails to abide by the conditions prescribed herein, or if the authorized taking is having more than a negligible impact on the species or stock of affected marine mammals.

Request for Public Comments

We request comment on our analysis, the draft authorization, and any other aspect of this Notice of Proposed IHA for Navy's pier replacement activities. Please include with your comments any supporting data or literature citations to help inform our final decision on Navy's request for an MMPA authorization.

Dated: August 1, 2017.

Catherine Marzin,

Acting Deputy Director, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 2017–16453 Filed 8–3–17; 8:45 am]

BILLING CODE 3510–22–P

COMMODITY FUTURES TRADING COMMISSION

Agency Information Collection Activities Relating to Security Futures Products

AGENCY: Commodity Futures Trading Commission.

ACTION: Notice.

SUMMARY: The Commodity Futures Trading Commission (''Commission'' or ''CFTC'') is announcing an opportunity for public comment on the extension of a proposed collection of certain information by the agency. In compliance with the Paperwork Reduction Act of 1995, Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments, as described below, on the proposed Information Collection Request (''ICR'') relating to security futures products.

DATES: Comments must be submitted on or before October 3, 2017.

ADDRESSES: You may submit comments, identified by OMB Control No. 3038–0059 by any of the following methods:

- The Agency's Web site, at *http://comments.cftc.gov/.* Follow the instructions for submitting comments through the Web site.
- *Mail:* Christopher Kirkpatrick, Secretary of the Commission, Commodity Futures Trading Commission, 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 through the Portal.

Please submit your comments using only one method.

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 you believe is 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 *http://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 ICR 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: David Steinberg, Associate Director, Division of Market Oversight, Commodity Futures Trading Commission, (202) 418–5102; email: *dsteinberg@cftc.gov,* and refer to OMB Control No. 3038–0059.

SUPPLEMENTARY INFORMATION: Under the PRA, Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of Information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3 and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA, 44 U.S.C. 3506(c)(2)(A), requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, the CFTC is publishing notice of the proposed collection of information listed below.

Title: Part 41, Relating to Security Futures Products (OMB Control No. 3038–0059). This is a request for extension of a currently approved information collection.

[1] 17 CFR 145.9.

Affected Entities: Entities potentially affected by this action are businesses and other for-profit institutions.

Abstract: Section 4d(c) of the Commodity Exchange Act (''CEA''), 7 U.S.C. 6d(c), requires the CFTC to consult with the Securities and Exchange Commission (''SEC'') and issue such rules, regulations, or orders as are necessary to avoid duplicative or conflicting regulations applicable to firms that are fully registered with the SEC as brokers or dealers and the CFTC as futures commission merchants involving provisions of the CEA that pertain to the treatment of customer funds. The CFTC, jointly with the SEC, issued regulations requiring such dually-registered firms to make choices as to how its customers' transactions in security futures products will be treated, either as securities transactions held in a securities account or as futures transactions held in a futures account. How an account is treated is important in the unlikely event of the insolvency of the firm. Securities accounts receive insurance protection under provisions of the Securities Investor Protection Act. By contrast, futures accounts are subject to the protections provided by the segregation requirements of the CEA.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for the CFTC's regulations were published on December 30, 1981. See 46 FR 63035 (Dec. 30, 1981).

The Commission would like to solicit comments to:

- 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 a practical use;
- Evaluate the accuracy of the Commission's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Enhance the quality, usefulness, and clarity of the information to be collected; and
- Minimize the burden of 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.

Burden Statement: The respondent burden for this collection is estimated to average 1.57 hours per response. This estimate includes the time needed to review instructions; develop, acquire,

install, and utilize technology and systems for the purposes of collecting, validating, and verifying information, processing and maintaining information and disclosing and providing information; adjust the existing ways to comply with any previously applicable instructions and requirements; train personnel to be able to respond to a collection of information; and transmit or otherwise disclose the information.

Respondents/Affected Entities: 44.

Estimated Number of Responses: 943.

Estimated Total Annual Burden on Respondents: 1,482 hours.

Frequency of Collection: On occasion.

The regulations require no new start-up or operations and maintenance costs.

Dated: August 1, 2017.

Robert N. Sidman,

Deputy Secretary of the Commission.

[FR Doc. 2017–16459 Filed 8–3–17; 8:45 am]

BILLING CODE 6351–01–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Docket ID: DOD–2017–OS–0011]

Submission for OMB Review; Comment Request

ACTION: 30-Day information collection notice.

SUMMARY: The Department of Defense has submitted to OMB for clearance, the following proposal for collection of information under the provisions of the Paperwork Reduction Act.

DATES: Consideration will be given to all comments received by September 5, 2017.

ADDRESSES: Comments and recommendations on the proposed information collection should be emailed to Ms. Jasmeet Seehra, DoD Desk Officer, at *Oira_submission@omb.eop.gov.* Please identify the proposed information collection by DoD Desk Officer and the Docket ID number and title of the information collection.

FOR FURTHER INFORMATION CONTACT: Fred Licari, 571–372–0493, or *whs.mc-alex.esd.mbx.dd-dod-information-collections@mail.mil.*

SUPPLEMENTARY INFORMATION:

Title, Associated Form and OMB Number: Federal Write-In Absentee Ballot (FWAB); Standard Form 186; OMB Control Number 0704–0502.

Type of Request: Reinstatement.

Number of Respondents: 1,200,000.

Responses per Respondent: 1.

Annual Responses: 1,200,000.

Average Burden per Response: 15 minutes.

Annual Burden Hours: 300,000.

Needs and Uses: The information collection requirement is necessary to fulfil the obligations of the Uniformed and Overseas Citizens Absentee Voting Act (UOCAVA), 52 U.S.C. 203, which requires the Secretary of Defense to prescribe official forms containing an absentee voter registration application, an absentee ballot request application, and a backup ballot. The forms are for use by the States to permit absent uniformed services voters and overseas voters to participate in general, special, primary and runoff elections for Federal office. The collected information will be retained by election officials to provide election materials, including absentee ballots, to the uniformed services, their eligible family members and overseas voters during the form's eligibility period provided by State law. No information from the Federal Write-In Absentee Ballot (FWAB) is collected or retained by the Federal government. The applicant is required to update and resubmit the information annually, whenever they change their mailing address or as otherwise required by State law. If the information is not submitted annually or whenever they change their mailing address, the applicant may not receive ballots for elections for Federal office in that calendar year.

Affected Public: Individuals or households.

Frequency: On occasion.

Respondent's Obligation: Voluntary.

OMB Desk Officer: Ms. Jasmeet Seehra.

You may also submit comments and recommendations, identified by Docket ID number and title, by the following method:

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

Instructions: All submissions received must include the agency name, Docket ID number and title for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the Internet at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

DOD Clearance Officer: Mr. Frederick Licari.

Written requests for copies of the information collection proposal should be sent to Mr. Licari at WHS/ESD Directives Division, 4800 Mark Center Drive, East Tower, Suite 03F09, Alexandria, VA 22350–3100.

Dated: July 31, 2017.

Aaron Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2017–16420 Filed 8–3–17; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Office of the Secretary

Department of Defense Military Family Readiness Council; Notice of Federal Advisory Committee Meeting

AGENCY: Under Secretary of Defense for Personnel and Readiness, DoD.

ACTION: Notice of Federal Advisory Committee meeting.

SUMMARY: The Department of Defense (DoD) is publishing this notice to announce that the following Federal Advisory Committee meeting of the Department of Defense Military Family Readiness Council will take place.

DATES: This meeting is open to the public and will be held on Tuesday, August 29, 2017 from 1:00 p.m. to 3:00 p.m.

ADDRESSES: 1155 Defense Pentagon PLC2 Pentagon Library and Conference Center, Room B6, Washington, DC 20301.

FOR FURTHER INFORMATION CONTACT: Ms. Melody McDonald or Dr. Randy Eltringham, (571) 372–0880 (Voice); (571) 372–5315 (Voice); (571) 372–0884 (Facsimile); OSD Pentagon OUSD P–R Mailbox Family Readiness Council, *osd.pentagon.ousd-p-r.mbx.family-readiness-council@mail.mil* (Email). Mailing address is Office of the Deputy Assistant Secretary of Defense (Military Community & Family Policy), Office of Family Readiness Policy, 4800 Mark Center Drive, Alexandria, VA 22350–2300, Room 3G15. The Official DoD MFRC Web site can be found at *http://www.militaryonesource.mil/service-providers/mfrc.*

SUPPLEMENTARY INFORMATION: This meeting is being held under the provisions of the Federal Advisory Committee Act (FACA) of 1972 (5 U.S.C., Appendix, as amended), the Government in the Sunshine Act of 1976 (5 U.S.C. 552b, as amended), and 41 CFR 102–3.140 and 102–3.150.

Purpose of the Meeting: This is the third and final meeting of the Council for FY2017. During this meeting, Council members will: (1) Review written public submissions and DoD and Military Services military family readiness related policy issuances that were published between August 1, 2016 and July 31, 2017; (2) Discuss and vote

on recommendations to be forwarded to the Secretary of Defense. [*Note:* Draft recommendations will focus on topics reviewed by the Council during FY2017. Topics include services provided to Special Needs Families (medical, family and state-liaison support) and Community Collaboratives and Partnerships as a strategy for meeting Service and family member information, referral and service delivery needs.]; and (3) Make recommendations for areas on which the Council should focus during FY2018.

Agenda

Welcome & Administrative Remarks.

Review of Written Public Submissions.

Review of Military Family Readiness Related Policy Issuances.

Presentation and Voting on MFRC Recommendations for the Secretary of Defense.

Closing Remarks: Looking Ahead to FY2018.

Note: Exact order may vary.

Meeting Accessibility: Pursuant to 5 U.S.C. 552b and 41 CFR 102–3.140 through 102–3.165, this meeting is open to the public, subject to the availability of space, on an RSVP list basis. Members of the public who are entering the Pentagon should arrive at the Pentagon Visitors Center waiting area (Pentagon Metro Entrance) at 12:00 p.m. on the day of the meeting to allow time to pass through security check points and to be escorted to the meeting location. Members of the public need to email their RSVP to the Council at *osd.pentagon.ousd-p-r.mbx.family-readiness-council@mail.mil* no later than 5:00 p.m. on Tuesday, August 22, 2017 to confirm seating availability and to request an escort or a handicapped accessible transportation cart if needed.

Written Statements: Interested persons may submit a written statement for review and consideration by the Council Chair and members. Written statements must not be longer than two type-written pages and should address the following details: The issue, discussion, and a recommended course of action. Additionally, those who make submissions are requested to avoid including personal identifiable information (PII) such as names of adults and children, phone numbers, addresses, social security numbers, etc.). Supporting documentation may also be included, as needed, to establish the appropriate historical context and to provide any necessary background information. Written submissions should be sent to the Council mailbox at *osd.pentagon.ousd-p-r.mbx.family-readiness-council@mail.mil* at least five (5) business days prior to the date of this meeting. If the written statement is not received at least five (5) business days prior to the meeting, the Designated Federal Officer (DFO) for the Council may choose to postpone consideration of the statement until the next open meeting of the Council. The DFO will review all timely submissions with the Council Chairman and ensure submitted written statements are provided to all members of the Council prior to the meeting that is subject to this notice.

Dated: July 31, 2017.

Aaron Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2017–16418 Filed 8–3–17; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF ENERGY

Office of Energy Efficiency and Renewable Energy

[Case No. RF–047]

Extension of Waiver to Panasonic Appliances Refrigeration Systems Corporation of America (PAPRSA) From the Department of Energy Consumer Refrigerator and Refrigerator-Freezer Test Procedures

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

ACTION: Extension of waiver.

SUMMARY: The U.S. Department of Energy (''DOE'') is granting a waiver extension (Case No. RF–047) to Panasonic Appliances Refrigeration Systems Corporation of America (''PAPRSA'') to waive the requirements of the DOE refrigerator and refrigerator-freezer test procedures for determining the energy consumption of a specific combination cooler-refrigerator basic model, PR5181WBC. Under this extension, PAPRSA is required to test and rate this basic model in accordance with the applicable DOE test procedure, with the exception that it must calculate energy consumption using a correction factor (''K-factor'') of 0.85.

DATES: This extension of waiver applies starting on August 4, 2017.

FOR FURTHER INFORMATION CONTACT:

Mr. Bryan Berringer, U.S. Department of Energy, Building Technologies Program, Mailstop EE–2J, 1000 Independence Avenue SW., Washington, DC 20585–0121. Telephone: (202) 586–0371, Email: *AS_Waiver_Requests@ee.doe.gov.*

Mr. Michael Kido, U.S. Department of Energy, Office of the General Counsel, Mail Stop GC–33, Forrestal Building, 1000 Independence Avenue SW., Washington, DC 20585–0103. Telephone: (202) 586–8145. Email: *Michael.Kido@hq.doe.gov.*

SUPPLEMENTARY INFORMATION: In accordance with 10 CFR 430.27(g), DOE gives notice of the issuance of its extension of waiver as set forth below. The extension of waiver grants PAPRSA a waiver from the applicable consumer refrigerator and refrigerator-freezer test procedures found in 10 CFR part 430, subpart B, appendix A for combination cooler-refrigerator basic model, PR5181WBC, provided that PAPRSA tests and rates the basic model using the alternate test procedure described in this notice. This extension prohibits PAPRSA from making representations concerning the energy efficiency of these products unless the product has been tested in a manner consistent with the provisions and restrictions in the alternate test procedure set forth in the extension below, and the representations fairly disclose those test results. Distributors, retailers, and private labelers are held to the same standard when making representations regarding the energy efficiency of these products. 42 U.S.C. 6293(c).

I. Background and Authority

Title III, Part B of the Energy Policy and Conservation Act of 1975, as amended (''EPCA'') (42 U.S.C. 6291–6309) established the Energy Conservation Program for Consumer Products Other Than Automobiles, a program that includes consumer refrigerators and refrigerator-freezers.[1] Part B includes definitions, test procedures, labeling provisions, energy conservation standards, and the authority to require information and reports from manufacturers. Further, Part B authorizes the Secretary of Energy to prescribe test procedures that are reasonably designed to produce results that measure energy efficiency, energy use, or estimated operating costs, and that are not unduly burdensome to conduct. (42 U.S.C. 6293(b)(3)) The test procedure for refrigerators and refrigerator-freezers is set forth in 10 CFR part 430, subpart B, appendix A.

The regulations set forth in 10 CFR 430.27 contain provisions that allow a person to seek a waiver from the test procedure requirements for a particular basic model of a type of covered product when the petitioner's basic model for which the petition for waiver was submitted contains one or more design characteristics that: (1) Prevent testing

[1] For editorial reasons, upon codification in the U.S. Code, Part B was re-designated Part A.

according to the prescribed test procedure, or (2) cause the prescribed test procedures to evaluate the basic model in a manner so unrepresentative of its true energy consumption characteristics as to provide materially inaccurate comparative data. 10 CFR 430.27(a)(1). DOE may grant the waiver subject to conditions, including adherence to alternate test procedures. 10 CFR 430.27(f)(2). DOE recently published standards for miscellaneous refrigeration products (''MREFs''). See 81 FR 75194 (Oct. 28, 2016). Testing to demonstrate compliance with those standards will require manufacturers to use the MREF test procedure established in a final rule published in July 2016. See 81 FR 46768 (July 18, 2016) (MREF coverage determination and test procedure final rule) and 81 FR 49868 (July 29, 2016) (MREF test procedure final rule correction notice). Under these rules, DOE has determined that products such as those that are at issue here fall into the MREF category. Accordingly, consistent with these MREF-specific provisions, these products will be evaluated under prescribed procedures and against specified standards that are tailored to account for their particular characteristics.

A petitioner may request that DOE extend the scope of a waiver or an interim waiver to include additional basic models employing the same technology as the basic model(s) set forth in the original petition. DOE will publish any such extension in the **Federal Register**. 10 CFR 430.27(g).

II. PAPRSA's Extension of Waiver: Assertions and Determinations

DOE issued a Decision and Order, in Case No. RF–022, granting PAPRSA [2] a waiver to test hybrid wine chiller/beverage center basic models (77 FR 49443 (August 16, 2012)). That waiver was extended to include additional basic models in Case Nos. RF–031 (78 FR 57139 (September 17, 2013)) and RF–041 (79 FR 55769 (September 17, 2014)). In Case No. RF–043, DOE issued an Order rescinding the Orders in Case Nos. RF–022, RF–031, and RF–041 due to erroneous formulae and reference to an obsolete DOE test procedure. That Order granted an interim waiver that covered all the basic models that were subject to the previous Orders, and one additional basic model for which PAPRSA had requested a waiver extension (81 FR 4270 (January 26, 2016)). Most recently, DOE issued a Decision and Order granting a waiver to all the basic models that had been subject to the interim waiver (82 FR 21209 (May 5, 2017)). The waiver required PAPRSA to test and rate the specified basic models in accordance with the applicable DOE test procedure, with the exception that it must calculate energy consumption using a correction factor (''K-factor'') of 0.85.

On May 3, 2017, PAPRSA requested an extension of that waiver, under 10 CFR 430.27(g), to a new basic model, PR5181WBC, that employs the same technology as the basic models set forth in the original petition for waiver. Specifically, PAPRSA states that basic model PR5181WBC employs the same wine compartment—beverage compartment technology and design characteristics as the basic models for which the original waiver was granted. That basic model achieves a wine-chiller compartment average temperature of 50 °F using a heater that prevents the wine-chiller compartment temperature from sinking below 42 °F. DOE is publishing at the end of this notice PAPRSA's request for extension of waiver in its entirety.

III. Order

After careful consideration of all the material submitted by PAPRSA, it is *ordered* that:

(1) The request for extension of waiver submitted by the Panasonic Appliances Refrigeration Systems Corporation of America (Case No. RF–047) is hereby granted as set forth in the paragraphs below.

(2) PAPRSA must test and rate the PAPRSA basic models specified in paragraph (3) using the current test procedure contained in 10 CFR part 430, subpart B, appendix A, with the exception that it must calculate energy consumption using a correction factor (''K-factor'') of 0.85.

Therefore, the energy consumption is defined by:

If compartment temperatures are below their respective standardized temperatures for both test settings (according to 10 CFR part 430, subpart B, appendix A, sec. 6.2.4.1):

$E = (ET1 \times 0.85) + IET.$

If compartment temperatures are not below their respective standardized temperatures for both test settings, the higher of the two values calculated by the following two formulas (according to 10 CFR part 430, subpart B, appendix A, sec. 6.2.4.2):

Energy consumption of the ''cooler compartment'':

$ECooler\ Compartment = (ET1 + [(ET2 - ET1) \times (55\ °F - TW1)/(TW2 - TW1)]) \times 0.85 + IET$

Energy consumption of the ''fresh food compartment'':

$EFreshFood\ Compartment = (ET1 + [(ET2–ET1) \times (39\ °F–TBC1)/(TBC2–TBC1)]) \times 0.85 + IET.$

(3) This Order only applies to basic model PR5181WBC.

(4) Representations. PAPRSA may make representations about the energy use of its combination cooler-refrigerator product for compliance, marketing, or other purposes only to the extent that such products have been tested in accordance with the provisions above and such representations fairly disclose the results of such testing.

(5) This Order will terminate on October 28, 2019, in conjunction with the compliance date that applies to the recently published standards for miscellaneous refrigeration products (''MREFs''). See 81 FR 75194 (Oct. 28, 2016). Testing to demonstrate compliance with those standards must be performed in accordance with the MREF test procedure final rule. See 81 FR 46768 (July 18, 2016) (MREF test procedure final rule) and 81 FR 49868 (July 29, 2016) (MREF test procedure final rule correction notice).

(6) This waiver is issued on the condition that the statements, representations, and documentary materials provided by the petitioner are valid. DOE may revoke or modify this waiver at any time if it determines the factual basis underlying the petition for waiver is incorrect, or the results from the alternate test procedure are unrepresentative of the basic models' true energy consumption characteristics.

(7) Granting of this extension does not release a petitioner from the certification requirements set forth at 10 CFR part 429.

Issued in Washington, DC, on July 28, 2017.

Kathleen B. Hogan,

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

[FR Doc. 2017–16447 Filed 8–3–17; 8:45 am]

BILLING CODE 6450–01–P

[2] The waiver was originally issued to Sanyo E&E Corporation, which has since changed its corporate name to PAPRSA.

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Notice of Commissioner and Staff Attendance at North American Electric Reliability Corporation Meetings

The Federal Energy Regulatory Commission (Commission) hereby gives

notice that members of the Commission and/or Commission staff may attend the following meetings:

North American Electric Reliability Corporation, Member Representatives Committee and Board of Trustees Meetings, Board of Trustees Corporate Governance and Human Resources Committee, Finance and Audit Committee, Compliance Committee, and Standards Oversight and Technology Committee Meetings.

The Westin Ottawa, 11 Colonel By Drive, Ottawa, ON K1N 9H4 Canada.

August 9 (8:00 a.m.–5:00 p.m. eastern time) and August 10 (8:30 a.m.–12:00 p.m. eastern time), 2017.

Further information regarding these meetings may be found at: *http://www.nerc.com/Pages/Calendar.aspx.*

The discussions at the meetings, which are open to the public, may address matters at issue in the following Commission proceedings:

Docket No. RR15–2, North American Electric Reliability Corporation
Docket No. RR17–6, North American Electric Reliability Corporation

For further information, please contact Jonathan First, 202–502–8529, or *jonathan.first@ferc.gov.*

Dated: July 31, 2017.

Kimberly D. Bose,

Secretary.

[FR Doc. 2017–16477 Filed 8–3–17; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #1

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER10–3246–012; ER10–2475–018; ER10–2474–018; ER13–1266–014; ER11–2044–022.

Applicants: PacifiCorp, Nevada Power Company, Sierra Pacific Power Company, CalEnergy, LLC, MidAmerican Energy Company.

Description: Notice of Non-Material Change in Status of the BHE MBR Sellers.

Filed Date: 7/28/17.

Accession Number: 20170728–5155.

Comments Due: 5 p.m. ET 8/18/17.

Docket Numbers: ER16–1456–008.

Applicants: Talen Energy Marketing, LLC.

Description: Compliance filing: Compliance Filing Cancelling Reactive Tariff to be effective 12/1/2016.

Filed Date: 7/28/17.

Accession Number: 20170728–5073.

Comments Due: 5 p.m. ET 8/18/17.

Docket Numbers: ER17–215–000.

Applicants: Midcontinent Independent System Operator, Inc., Great River Energy, South Mississippi Electric Power Association.

Description: Report Filing: 2017–07–28_Submittal of ROE refund report in Docket No. EL14–12 to be effective N/A.

Filed Date: 7/28/17.

Accession Number: 20170728–5154.

Comments Due: 5 p.m. ET 8/18/17.

Docket Numbers: ER17–1712–001.

Applicants: Midcontinent Independent System Operator, Inc.

Description: Tariff Amendment: 2017–07–28_Amendment to Compensation for Manual Redispatch Filing to be effective 12/31/9998.

Filed Date: 7/28/17.

Accession Number: 20170728–5065.

Comments Due: 5 p.m. ET 8/18/17.

Docket Numbers: ER17–2038–002.

Applicants: Southwest Power Pool, Inc.

Description: Tariff Amendment: 2198R23 Kansas Power Pool NITSA NOA to be effective 9/1/2017.

Filed Date: 7/27/17.

Accession Number: 20170727–5179.

Comments Due: 5 p.m. ET 8/17/17.

Docket Numbers: ER17–2170–000.

Applicants: San Diego Gas & Electric Company.

Description: Baseline eTariff Filing: Palo Verde North Gila Line ANPP High Voltage Switchyard Interconnection Agreement to be effective 7/28/2017.

Filed Date: 7/27/17.

Accession Number: 20170727–5152.

Comments Due: 5 p.m. ET 8/17/17.

Docket Numbers: ER17–2171–000.

Applicants: Southern California Edison Company.

Description: § 205(d) Rate Filing: Amended LGIA Willow Springs Solar, LLC to be effective 7/28/2017.

Filed Date: 7/27/17.

Accession Number: 20170727–5153.

Comments Due: 5 p.m. ET 8/17/17.

Docket Numbers: ER17–2172–000.

Applicants: Southern California Edison Company.

Description: § 205(d) Rate Filing: Amended LGIA North Rosamond Solar, LLC to be effective 7/28/2017.

Filed Date: 7/27/17.

Accession Number: 20170727–5156.

Comments Due: 5 p.m. ET 8/17/17.

Docket Numbers: ER17–2173–000.

Applicants: Cedar Creek II, LLC.

Description: § 205(d) Rate Filing: Revised Market-Based Rate Tariff to be effective 9/27/2017.

Filed Date: 7/28/17.

Accession Number: 20170728–5059.

Comments Due: 5 p.m. ET 8/18/17.

Docket Numbers: ER17–2174–000.

Applicants: Southwest Power Pool, Inc.

Description: § 205(d) Rate Filing: 1139R5 Southwestern Public Service Company NITSA NOA to be effective 7/1/2017.

Filed Date: 7/28/17.

Accession Number: 20170728–5072.

Comments Due: 5 p.m. ET 8/18/17.

Docket Numbers: ER17–2175–000.

Applicants: Susquehanna Nuclear, LLC.

Description: Compliance filing: Baseline Reactive Tariff for Susquehanna Nuclear, LLC (ER16–1456) to be effective 12/1/2016.

Filed Date: 7/28/17.

Accession Number: 20170728–5167.

Comments Due: 5 p.m. ET 8/18/17.

Docket Numbers: ER17–2176–000.

Applicants: Brunner Island, LLC.

Description: Compliance filing: Baseline Reactive Tariff for Brunner Island, LLC (ER16–1456) to be effective 12/1/2016.

Filed Date: 7/28/17.

Accession Number: 20170728–5172.

Comments Due: 5 p.m. ET 8/18/17.

Docket Numbers: ER17–2177–000.

Applicants: Martins Creek, LLC.

Description: Compliance filing: Baseline Reactive Tariff for Martins Creek, LLC (ER16–1456) to be effective 12/1/2016.

Filed Date: 7/28/17.

Accession Number: 20170728–5181.

Comments Due: 5 p.m. ET 8/18/17.

Docket Numbers: ER17–2178–000.

Applicants: Montour, LLC.

Description: Compliance filing: Baseline Reactive Tariff for Montour, LLC (ER16–1456) to be effective 12/1/2016.

Filed Date: 7/28/17.

Accession Number: 20170728–5195.

Comments Due: 5 p.m. ET 8/18/17.

The filings are accessible in the Commission's eLibrary system by clicking on the links or querying the docket number.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings

can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: July 28, 2017.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2017–16460 Filed 8–3–17; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #1

Take notice that the Commission received the following electric corporate filings:

Docket Numbers: EC17–142–000.

Applicants: Exelon Generation Company, LLC, Exelon FitzPatrick, LLC.

Description: Joint Application for Authorization Under Section 203 of the FPA of Exelon Generation Company, LLC, et. al.

Filed Date: 7/28/17.

Accession Number: 20170728–5234.

Comments Due: 5 p.m. ET 8/18/17.

Take notice that the Commission received the following exempt wholesale generator filings:

Docket Numbers: EG17–131–000.

Applicants: Cap Ridge Wind I, LLC.

Description: Notice of Self-Certification of Exempt Wholesale Generator Status of Cap Ridge Wind I, LLC.

Filed Date: 7/28/17.

Accession Number: 20170728–5243.

Comments Due: 5 p.m. ET 8/18/17.

Docket Numbers: EG17–132–000.

Applicants: Cap Ridge Wind II, LLC.

Description: Notice of Self-Certification of Exempt Wholesale Generator Status of Cap Ridge Wind II, LLC.

Filed Date: 7/28/17.

Accession Number: 20170728–5245.

Comments Due: 5 p.m. ET 8/18/17.

Docket Numbers: EG17–133–000.

Applicants: Cap Ridge Wind III, LLC.

Description: Notice of Self-Certification of Exempt Wholesale Generator Status of Cap Ridge Wind III, LLC.

Filed Date: 7/28/17.

Accession Number: 20170728–5246.

Comments Due: 5 p.m. ET 8/18/17.

Docket Numbers: EG17–134–000.

Applicants: Cap Ridge Wind IV, LLC.

Description: Notice of Self-Certification of Exempt Wholesale Generator Status of Cap Ridge Wind IV, LLC.

Filed Date: 7/28/17.

Accession Number: 20170728–5248.

Comments Due: 5 p.m. ET 8/18/17.

Docket Numbers: EG17–135–000.

Applicants: Cap Ridge Interconnection, LLC.

Description: Notice of Self-Certification of Exempt Wholesale Generator Status of Cap Ridge Interconnection, LLC.

Filed Date: 7/28/17.

Accession Number: 20170728–5249.

Comments Due: 5 p.m. ET 8/18/17.

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER10–2794–023; ER14–2672–008; ER12–1825–021.

Applicants: EDF Trading North America, LLC, EDF Energy Services, LLC, EDF Industrial Power Services (CA), LLC.

Description: Notice of Non-Material Change in Status of EDF Trading North America, LLC, et al.

Filed Date: 7/28/17.

Accession Number: 20170728–5233.

Comments Due: 5 p.m. ET 8/18/17.

Docket Numbers: ER17–2179–000.

Applicants: California Independent System Operator Corporation.

Description: § 205(d) Rate Filing: 2017–07–28 Remove Conceptual Statewide Plan Amendment to be effective 9/27/2017.

Filed Date: 7/28/17.

Accession Number: 20170728–5211.

Comments Due: 5 p.m. ET 8/18/17.

Docket Numbers: ER17–2180–000.

Applicants: Southwest Power Pool, Inc.

Description: § 205(d) Rate Filing: Attachment AE Revisions Regarding Staggered Start Resources to be effective 10/1/2017.

Filed Date: 7/28/17.

Accession Number: 20170728–5222.

Comments Due: 5 p.m. ET 8/18/17.

Docket Numbers: ER17–2181–000.

Applicants: Pacific Gas and Electric Company.

Description: § 205(d) Rate Filing: Q2 2017 Quarterly Filing of City and County of San Francisco's WDT SA (SA 275) to be effective 6/30/2017.

Filed Date: 7/31/17.

Accession Number: 20170731–5000.

Comments Due: 5 p.m. ET 8/21/17.

Docket Numbers: ER17–2182–000.

Applicants: Coyote Canyon Energy LLC.

Description: Tariff Cancellation: Coyote Canyon Energy MBR Tariff Cancellation to be effective 9/30/2017.

Filed Date: 7/31/17.

Accession Number: 20170731–5020.

Comments Due: 5 p.m. ET 8/21/17.

Docket Numbers: ER17–2183–000.

Applicants: Duke Energy Progress, LLC

Description: Tariff Cancellation: Cancellation of CCCP IA (OATT SA 206) to be effective 8/1/2017.

Filed Date: 7/31/17.

Accession Number: 20170731–5035.

Comments Due: 5 p.m. ET 8/21/17.

The filings are accessible in the Commission's eLibrary system by clicking on the links or querying the docket number.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: July 31, 2017.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2017–16457 Filed 8–3–17; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER17–2162–000]

SunE Beacon Site 2 LLC; Supplemental Notice That Initial Market-Based Rate Filing Includes Request for Blanket Section 204 Authorization

This is a supplemental notice in the above-referenced proceeding SunE Beacon Site 2 LLC's application for market-based rate authority, with an accompanying rate tariff, noting that such application includes a request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability.

Any person desiring to intervene or to protest should file with the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant.

Notice is hereby given that the deadline for filing protests with regard to the applicant's request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability, is August 17, 2017.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at *http://www.ferc.gov.* To facilitate electronic service, persons with Internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

Persons unable to file electronically should submit an original and 5 copies of the intervention or protest to the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426.

The filings in the above-referenced proceeding are accessible in the Commission's eLibrary system by clicking on the appropriate link in the above list. They are also available for electronic review in the Commission's Public Reference Room in Washington, DC. There is an eSubscription link on the Web site that enables subscribers to receive email notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please email *FERCOnlineSupport@ferc.gov* or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2017–16463 Filed 8–3–17; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER17–2163–000]

SunE Beacon Site 5, LLC; Supplemental Notice That Initial Market-Based Rate Filing Includes Request for Blanket Section 204 Authorization

This is a supplemental notice in the above-referenced proceeding SunE Beacon Site 5 LLC's application for market-based rate authority, with an accompanying rate tariff, noting that such application includes a request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability.

Any person desiring to intervene or to protest should file with the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant.

Notice is hereby given that the deadline for filing protests with regard to the applicant's request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability, is August 17, 2017.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at *http://www.ferc.gov.* To facilitate electronic service, persons with Internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

Persons unable to file electronically should submit an original and 5 copies of the intervention or protest to the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426.

The filings in the above-referenced proceeding are accessible in the Commission's eLibrary system by clicking on the appropriate link in the above list. They are also available for electronic review in the Commission's Public Reference Room in Washington, DC. There is an eSubscription link on the Web site that enables subscribers to receive email notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please email *FERCOnlineSupport@ferc.gov* or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: July 28, 2017.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2017–16464 Filed 8–3–17; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #2

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER16–372–005.
Applicants: PJM Interconnection, L.L.C.
Description: Compliance filing: Amendment to Compliance Filing in Docket No. ER16–372–003 to be effective 5/15/2017.
Filed Date: 7/31/17.
Accession Number: 20170731–5118.
Comments Due: 5 p.m. ET 8/21/17.

Docket Numbers: ER17–1649–001.
Applicants: Florida Power & Light Company.
Description: Tariff Amendment: Errata to the Original Point to Point Transmission Service Agreement No. 274 to be effective 10/1/2017.
Filed Date: 7/31/17.
Accession Number: 20170731–5222.
Comments Due: 5 p.m. ET 8/21/17.

Docket Numbers: ER17–2184–000.
Applicants: New England Power Pool Participants Committee.
Description: § 205(d) Rate Filing: Aug 2017 Membership Filing to be effective 8/1/2017.
Filed Date: 7/31/17.
Accession Number: 20170731–5131.
Comments Due: 5 p.m. ET 8/21/17.

Docket Numbers: ER17–2185–000.
Applicants: Great Valley Solar 1, LLC.
Description: Initial rate filing: Great Valley Solar 1, LLC Shared Facilities Agreement to be effective 10/1/2017.
Filed Date: 7/31/17.
Accession Number: 20170731–5135
Comments Due: 5 p.m. ET 8/21/17.

Docket Numbers: ER17–2186–000.
Applicants: Madison Paper Industries.
Description: Tariff Cancellation: cancellation filing to be effective 8/1/2017.
Filed Date: 7/31/17.
Accession Number: 20170731–5136.
Comments Due: 5 p.m. ET 8/21/17.

Docket Numbers: ER17–2187–000.
Applicants: Southern California Edison Company.
Description: Tariff Cancellation: Notice of Cancellation of ETCs for Azusa, Banning & Colton to be effective 9/30/2017.
Filed Date: 7/31/17.
Accession Number: 20170731–5137.
Comments Due: 5 p.m. ET 8/21/17.

Docket Numbers: ER17–2188–000.
Applicants: Playa Solar 1, LLC.
Description: Baseline eTariff Filing: Playa Solar 1 Notice of Change in Status

and Request for Notice Waiver to be effective 8/1/2017.

Filed Date: 7/31/17.

Accession Number: 20170731–5147.

Comments Due: 5 p.m. ET 8/21/17.

Docket Numbers: ER17–2189–000.

Applicants: Playa Solar 2, LLC.

Description: Baseline eTariff Filing: Playa Solar 2 Notice of Change in Status and Request for Notice Waiver to be effective 8/1/2017.

Filed Date: 7/31/17.

Accession Number: 20170731–5152.

Comments Due: 5 p.m. ET 8/21/17.

Docket Numbers: ER17–2190–000.

Applicants: Playa Solar 1, LLC.

Description: § 205(d) Rate Filing: Playa 1 Refiling of SFA Under New Tariff Identifier—Notice Waiver Requested to be effective 8/1/2017.

Filed Date: 7/31/17.

Accession Number: 20170731–5161.

Comments Due: 5 p.m. ET 8/21/17.

Docket Numbers: ER17–2191–000.

Applicants: PJM Interconnection, L.L.C.

Description: § 205(d) Rate Filing: 2nd Quarter 2017 Updates to OA–RAA Member Lists to be effective 6/30/2017.

Filed Date: 7/31/17.

Accession Number: 20170731–5166.

Comments Due: 5 p.m. ET 8/21/17.

Docket Numbers: ER17–2192–000.

Applicants: Playa Solar 1, LLC.

Description: Tariff Cancellation: Complete Cancellation of Playa Solar 1 MBR Program Tariff Identifier to be effective 8/1/2017.

Filed Date: 7/31/17.

Accession Number: 20170731–5169.

Comments Due: 5 p.m. ET 8/21/17.

Docket Numbers: ER17–2193–000.

Applicants: Great Valley Solar 1, LLC.

Description: Initial rate filing: Great Valley Solar 1, LLC LGIA Co-Tenancy Agreement to be effective 10/1/2017.

Filed Date: 7/31/17.

Accession Number: 20170731–5170.

Comments Due: 5 p.m. ET 8/21/17.

Docket Numbers: ER17–2194–000.

Applicants: Playa Solar 2, LLC.

Description: § 205(d) Rate Filing: Playa 2 Refiling of SFA Under New Tariff Identifier—Notice Waiver Request to be effective 8/1/2017.

Filed Date: 7/31/17.

Accession Number: 20170731–5171.

Comments Due: 5 p.m. ET 8/21/17.

Docket Numbers: ER17–2195–000.

Applicants: PJM Interconnection, L.L.C.

Description: § 205(d) Rate Filing: Service Agreement Nos. 4518 and 4756, Queue No. W4–005 Phase I and II to be effective 6/30/2017.

Filed Date: 7/31/17.

Accession Number: 20170731–5172.

Comments Due: 5 p.m. ET 8/21/17.

Docket Numbers: ER17–2196–000.

Applicants: Playa Solar 2, LLC.

Description: Tariff Cancellation: Complete Cancellation of Playa Solar 2 MBR Program Tariff Identifier to be effective 8/1/2017.

Filed Date: 7/31/17.

Accession Number: 20170731–5174.

Comments Due: 5 p.m. ET 8/21/17.

Docket Numbers: ER17–2197–000.

Applicants: Nevada Power Company.

Description: § 205(d) Rate Filing: Rate Schedule No. 155 NPC/CRC Agreement to be effective 10/1/2017.

Filed Date: 7/31/17.

Accession Number: 20170731–5176.

Comments Due: 5 p.m. ET 8/21/17.

Docket Numbers: ER17–2198–000.

Applicants: Central Maine Power Company.

Description: § 205(d) Rate Filing: First Amendment to Bucksport Generation LLC Interconnection Agreement to be effective 8/1/2017.

Filed Date: 7/31/17.

Accession Number: 20170731–5194.

Comments Due: 5 p.m. ET 8/21/17.

Docket Numbers: ER17–2199–000.

Applicants: Southwest Power Pool, Inc.

Description: § 205(d) Rate Filing: 3215R3 People's Electric Cooperative NITSA NOA to be effective 7/1/2017.

Filed Date: 7/31/17.

Accession Number: 20170731–5223.

Comments Due: 5 p.m. ET 8/21/17.

Docket Numbers: ER17–2200–000.

Applicants: PJM Interconnection, L.L.C.

Description: § 205(d) Rate Filing: Revisions to OATT Attachments O and P re: Solar Generation Meteorological Data to be effective 9/29/2017.

Filed Date: 7/31/17.

Accession Number: 20170731–5240.

Comments Due: 5 p.m. ET 8/21/17.

The filings are accessible in the Commission's eLibrary system by clicking on the links or querying the docket number.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: July 31, 2017.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2017–16458 Filed 8–3–17; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 2531–075–ME]

Brookfield White Pine Hydro LLC; Notice of Availability of Environmental Assessment

In accordance with the National Environmental Policy Act of 1969 and the Federal Energy Regulatory Commission's (Commission) regulations, 18 CFR part 380 (Order No. 486, 52 FR 47897), the Office of Energy Projects has reviewed the application for a new license for the West Buxton Hydroelectric Project, located on the Saco River in York and Cumberland Counties, Maine, and has prepared an Environmental Assessment (EA). The project does not occupy federal land.

The EA contains Commission staff's analysis of the potential effects of the project, and concludes that licensing the project, with appropriate environmental protective measures, would not constitute a major federal action that would significantly affect the quality of the human environment.

A copy of the EA is available for review at the Commission in the Public Reference Room, or may be viewed on the Commission's 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, contact FERC Online Support at *FERCOnlineSupport@ferc.gov,* or at (866) 208–3676 (toll free) or (202) 502–8659 (TTY).

You may also register online at *http://www.ferc.gov/docs-filing/esubscription.asp* to be notified via email of new filings and issuances related to this project or other pending projects. For assistance, contact FERC Online Support.

Any comments should be filed within 30 days from the date of this notice. The Commission strongly encourages electronic filing. Please file comments using the Commission's eFiling system at *http://www.ferc.gov/docs-filing/efiling.asp.* Commenters can submit brief comments up to 6,000 characters, without prior registration, using the

eComment system at *http://www.ferc.gov/docs-filing/ecomment.asp.* You must include your name and contact information at the end of your comments. For assistance, please contact FERC Online Support. In lieu of electronic filing, please send a paper copy to: Secretary, Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426. The first page of any filing should include docket number P–2531–075.

For further information, contact Allan Creamer at (202) 502–8365, or via email at *allan.creamer@ferc.gov.*

Dated: July 31, 2017.

Kimberly D. Bose,

Secretary.

[FR Doc. 2017–16478 Filed 8–3–17; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings

Take notice that the Commission has received the following Natural Gas Pipeline Rate and Refund Report filings:

Filings Instituting Proceedings

Docket Numbers: RP17–912–000.

Applicants: Algonquin Gas Transmission, LLC.

Description: Algonquin Gas Transmission, LLC submits tariff filing per 154.204: Negotiated Rates—Bay State to BBPC 794308 & 794309 to be effective 8/1/2017.

Filed Date: 07/24/2017.

Accession Number: 20170724–5047.

Comment Date: 5:00 p.m. Eastern Time on Monday, August 07, 2017.

Docket Numbers: RP17–914–000.

Applicants: Bluewater Gas Storage, LLC.

Description: Bluewater Gas Storage, LLC submits tariff filing per 154.204: Bluewater Ownership Update Filing July 2017 to be effective 6/30/2017.

Filed Date: 07/25/2017.

Accession Number: 20170725–5038.

Comment Date: 5:00 p.m. Eastern Time on Monday, August 07, 2017.

The filings are accessible in the Commission's eLibrary system by clicking on the links or querying the docket number.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated July 27, 2017.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2017–16461 Filed 8–3–17; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP17–476–000]

Gulf South Pipeline Company, LP; Notice of Application

Take notice that on July 20, 2017, Gulf South Pipeline Company, LP (Gulf South), 9 Greenway Plaza, Suite 2800, Houston, Texas 77046, filed an application pursuant to section 7(c) of the Natural Gas Act (NGA) and the Federal Energy Regulatory Commission's (Commission) regulations seeking authorization to construct, operate, and maintain: (1) A new 10,000 horsepower compressor station to be named the Westlake Compressor Station; (2) approximately 0.3 miles of 16-inch diameter natural gas pipeline; (3) a new delivery meter station; and (4) a new receipt meter station on an existing Gulf South facility site. These facilities are located in Calcasieu Parish, Louisiana, as more fully described in the application which is on file with the Commission and open to public inspection. The filing may also 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, (866) 208–3676 or TTY, (202) 502–8659.

Any questions regarding this application should be directed to Kathy D. Fort, Manager Certificates & Tariffs, Gulf South Pipeline Company, LP, 610 West Second Street, Owensboro, Kentucky, 42301, or call (270) 688–6825, or by email: *Kathy.fort@bwpmlp.com.*

Gulf South states the proposed Westlake Expansion Project will allow it to provide up to 200,000 dekatherms per day (Dth/d) of firm transportation service to Entergy Louisiana, LLC's proposed 980 megawatt natural gas-fired combined cycle electric generating unit to be located near Westlake, Louisiana.

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 for Environmental Review will serve to notify federal and state agencies of the timing for the completion of all necessary reviews, and the subsequent need to complete all federal authorizations within 90 days of the date of issuance of the Commission staff's FEIS or EA.

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 7 copies of filings made in the proceeding with the Commission and must mail a copy to the applicant and to every other party. 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 commentors 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 commentors will not be required to serve copies of filed documents on all other parties. However, the non-party commentors 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.

The Commission strongly encourages electronic filings of comments, protests and interventions in lieu of paper using the eFiling link at *http://www.ferc.gov.* Persons unable to file electronically should submit an original and 5 copies of the protest or intervention to the Federal Energy regulatory Commission, 888 First Street NE., Washington, DC 20426.

Comment Date: 5:00 p.m. Eastern Time on August 21, 2017.

Dated: July 31, 2017.

Kimberly D. Bose,

Secretary.

[FR Doc. 2017–16476 Filed 8–3–17; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. AD15–10–000]

Notice of Availability of the Final Guidelines for Reporting on Cultural Resources Investigations for Natural Gas Projects

The staff of the Federal Energy Regulatory Commission's (FERC or Commission) Office of Energy Projects has finalized its revised *Guidelines for Reporting on Cultural Resources Investigations for Natural Gas Projects* (*Guidelines*), which was issued in draft form on January 25, 2017, for comment. The *Guidelines* have been revised to provide updated guidance on communicating with federally recognized tribes; clarifications regarding off-the-record communications; documentation for Blanket Certificate Programs; and to address substantive comments received on the draft *Guidelines.*

The *Guidelines* can be found in Docket Number AD15–10–000. The full text of the *Guidelines* can be viewed on the Commission's Web site at *http://www.ferc.gov/industries/gas/enviro/guidelines.asp.*

The *Guidelines are* intended to provide guidance to the industry. This manual does not substitute for, amend, or supersede the Commission's regulations under the Natural Gas Act of 1938 or the Commission's and Council on Environmental Quality's regulations under the National Environmental Policy Act. It imposes no new legal obligations and grants no additional rights.

In response to the draft *Guidelines,* Commission staff received comments from federally recognized Indian tribes, industry representatives, federal and state agencies, and non-governmental organizations. Staff reviewed and considered each comment and modified several portions of the document in response. Staff declined to modify the document where comments either were too project- or location-specific to be included in general guidance, were already adequately/accurately addressed as written, or regarded topics that were not relevant to the *Guidelines.*

All of the information related to the proposed updates to the *Guidelines* and submitted comments can be found on the FERC Web site (*www.ferc.gov*) using the eLibrary link. Click on the eLibrary link, click on Docket Search and in the Docket Number field enter the docket number AD15–10, excluding the last three digits. 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 formal documents issued by the Commission, such as orders, notices, and rulemakings.

Dated: July 31, 2017.

Kimberly D. Bose,

Secretary.

[FR Doc. 2017–16475 Filed 8–3–17; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER17–2152–000]

Cottonwood Wind Project, LLC; Supplemental Notice That Initial Market-Based Rate Filing Includes Request for Blanket Section 204 Authorization

This is a supplemental notice in the above-referenced proceeding Cottonwood Wind Project, LLC 's application for market-based rate authority, with an accompanying rate tariff, noting that such application includes a request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability.

Any person desiring to intervene or to protest should file with the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant.

Notice is hereby given that the deadline for filing protests with regard to the applicant's request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability, is August 17, 2017.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at *http://www.ferc.gov.* To facilitate electronic service, persons with Internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

Persons unable to file electronically should submit an original and 5 copies of the intervention or protest to the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426.

The filings in the above-referenced proceeding are accessible in the Commission's eLibrary system by clicking on the appropriate link in the above list. They are also available for electronic review in the Commission's Public Reference Room in Washington, DC. There is an eSubscription link on the Web site that enables subscribers to receive email notification when a document is added to a subscribed

docket(s). For assistance with any FERC Online service, please email *FERCOnlineSupport@ferc.gov* or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: July 28, 2017.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2017–16462 Filed 8–3–17; 8:45 am]

BILLING CODE 6717–01–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–9965–55–OECA]

Applicability Determination Index (ADI) Data System Recent Posting: Agency Applicability Determinations, Alternative Monitoring Decisions, and Regulatory Interpretations Pertaining to Standards of Performance for New Stationary Sources, National Emission Standards for Hazardous Air Pollutants, and the Stratospheric Ozone Protection Program

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of availability.

SUMMARY: This action announces applicability determinations, alternative monitoring decisions, and regulatory interpretations that EPA has made under the New Source Performance Standards (NSPS); the National Emission Standards for Hazardous Air Pollutants (NESHAP); and/or the Stratospheric Ozone Protection Program.

FOR FURTHER INFORMATION CONTACT: An electronic copy of each complete document posted on the Applicability Determination Index (ADI) data system is available on the Internet through the Resources and Guidance Documents for Compliance Assistance page of the Clean Air Act Compliance Monitoring Web site under ''Air'' at: *https://www2.epa.gov/compliance/resources-and-guidance-documents-compliance-assistance.* The letters and memoranda on the ADI may be located by date, office of issuance, subpart, citation, control number, or by string word searches. For questions about the ADI or this notice, contact Maria Malave at EPA by phone at: (202) 564–7027, or by email at: *malave.maria@epa.gov.* For technical questions about individual applicability determinations or monitoring decisions, refer to the contact person identified in the individual documents, or in the absence of a contact person, refer to the author of the document.

SUPPLEMENTARY INFORMATION:

Background

The General Provisions of the NSPS in 40 Code of Federal Regulations (CFR) part 60 and the General Provisions of the NESHAP in 40 CFR part 61 provide that a source owner or operator may request a determination of whether certain intended actions constitute the commencement of construction, reconstruction, or modification. The EPA's written responses to these inquiries are commonly referred to as applicability determinations. See 40 CFR 60.5 and 61.06. Although the NESHAP part 63 regulations [which include Maximum Achievable Control Technology (MACT) standards and/or Generally Available Control Technology (GACT) standards] and Section 111(d) of the Clean Air Act (CAA) contain no specific regulatory provision providing that sources may request applicability determinations, the EPA also responds to written inquiries regarding applicability for the part 63 and Section 111(d) programs. The NSPS and NESHAP also allow sources to seek permission to use monitoring or recordkeeping that is different from the promulgated requirements. See 40 CFR 60.13(i), 61.14(g), 63.8(b)(1), 63.8(f), and 63.10(f).

The EPA's written responses to these inquiries are commonly referred to as alternative monitoring decisions. Furthermore, the EPA responds to written inquiries about the broad range of NSPS and NESHAP regulatory requirements as they pertain to a whole source category.

These inquiries may pertain, for example, to the type of sources to which the regulation applies, or to the testing, monitoring, recordkeeping, or reporting requirements contained in the regulation. The EPA's written responses to these inquiries are commonly referred to as regulatory interpretations.

The EPA currently compiles EPA-issued NSPS and NESHAP applicability determinations, alternative monitoring decisions, and regulatory interpretations, and posts them to the ADI on a regular basis. In addition, the ADI contains EPA-issued responses to requests pursuant to the stratospheric ozone regulations, contained in 40 CFR part 82. The ADI is a data system on the Internet with over three thousand EPA letters and memoranda pertaining to the applicability, monitoring, recordkeeping, and reporting requirements of the NSPS, NESHAP, and stratospheric ozone regulations. Users can search for letters and memoranda by date, office of issuance, subpart, citation, control number, or by string word searches.

Today's action comprises a summary of 31 such documents added to the ADI on July 21, 2017. This action lists the subject and header of each letter and memorandum, as well as a brief abstract of the letter or memorandum. Complete copies of these documents may be obtained from the ADI on the Internet through the through the Resources and Guidance Documents for Compliance Assistance page of the Clean Air Act Compliance Monitoring Web site under ''Air'' at: *https://www2.epa.gov/compliance/resources-and-guidance-documents-compliance-assistance.*

Summary of Headers and Abstracts

The following table identifies the database control number for each document posted on the ADI data system on July 21, 2017; the applicable category; the section(s) and/or subpart(s) of 40 CFR part 60, 61, or 63 (as applicable) addressed in the document; and the title of the document, which provides a brief description of the subject matter.

We have also included an abstract of each document identified with its control number after the table. These abstracts are provided solely to alert the public to possible items of interest and are not intended as substitutes for the full text of the documents. This action does not change the status of any document with respect to whether it is ''of nationwide scope or effect'' for purposes of CAA section 307(b)(1). For example, this document does not convert an applicability determination for a particular source into a nationwide rule. Neither does it purport to make a previously non-binding document binding.

ADI DETERMINATIONS UPLOADED ON JULY 21, 2017

Control No.	Categories	Subparts	Title
1600009	NSPS	Ja	Regulatory Interpretation on an Alternative Calibration Procedure for Hydrogen Sulfide Monitor at a Refinery.

ADI DETERMINATIONS UPLOADED ON JULY 21, 2017—Continued

Control No.	Categories	Subparts	Title
1600010	NSPS	Ec	Alternate Monitoring Operating Parameter Limits for Two Waste Incinerators.
1600011	NSPS	EEEE	Alternative Operating Parameter Limits for Commercial Incinerator.
1600012	NSPS	J, Ja	Alternative Monitoring Plan for Hydrogen Sulfide in Portable Temporary Thermal Oxidizer Units at Refineries.
1600013	NSPS	J, Ja	Alternative Monitoring Plan for Hydrogen Sulfide in Portable Temporary Thermal Oxidizer Units at Refineries.
1600018	NSPS	NNN, RRR	Regulatory Interpretation for a Biodiesel Manufacturing Facility.
1600027	NSPS	A, Ja	Alternative Monitoring Plan for Span Gas Concentration and High Range Validation Standards for H2S CEMS at a Refinery.
1600028	NSPS	J	Alternative Monitoring Plan for Revised Process Parameter Limits at a Refinery.
1600029	NSPS	A, Ec	Alternative Monitoring Operating Parameter Limits for Air Pollution Control System at a Medical Waste Incinerator.
1600030	NSPS	J	Withdrawal of Alternative Monitoring Plan for Sulfur Loading Vent Stream at a Refinery.
1600031	NSPS	J	Alternative Monitoring Plan Revision for Re-Routed Vent Gas Stream at a Refinery.
1600032	NSPS	Ja	Alternative Monitoring Plan for Flares at a Refinery.
1600033	NSPS	Ja	Alternative Monitoring Plan for a Flare at a Refinery.
1600034	NSPS	GG	Alternative Monitoring Plan for NO_X Emissions during Startup from Stationary Gas Turbines.
1600035	NSPS	JJJJ	Performance Test Waiver for Stationary Spark Ignition Internal Combustion Engines.
1600036	NSPS	UUU	Alternative Monitoring Plan for Bag Leak Detection System In Lieu of COMS at a Sand Reclamation Unit.
1600037	NSPS	UUU	Applicability Determination for Industrial Sand Dryer.
1600038	NSPS	Ja	Alternative Calibration Methods for Total Reduced Sulfur Analyzers at a Refinery.
1600039	NSPS	UUU	Alternative Monitoring Plan In Lieu of COMS at a Sand Reclamation Unit.
1600040	NSPS	UUU	Request for Exemption to Opacity Monitoring Requirements for Thermal Sand Reclamation Units.
1600041	NSPS	JJJJ	Alternative Test Method for Spark Ignition Engines.
A160001	Asbestos, NESHAP.	M	Waiver Request from Asbestos Testing for Bare Concrete Deck Bridges.
A160002	Asbestos, NESHAP.	M	Applicability Determination for Airport Taxiways.
M160005	MACT	XXXXXX	Applicability Determination for a Steel Foundry.
M160007	MACT, NESHAP	JJJJ, SSSSS	Applicability Determination for Mica Sheets Manufacturing.
M160009	MACT, NESHAP	VVVVVV	Applicability Determination for Pharmaceutical Manufacturing Facility.
M160017	MACT	JJJJ	Applicability Determination for Web Coating Manufacturing Facility.
M160019	MACT, NSPS	J, UUU	Alternative Monitoring Plan for Wet Gas Scrubber at a Refinery.
M160020	MACT, GACT, NESHAP, NSPS.	AAa, YYYYY, ZZZZZ.	Applicability Determination for a Steelmaking Facility.
M160021	MACT	JJJ	Alternative Monitoring Method In Lieu of Continuous Flow Monitor for a Thermal Oxidizer.
Z160005	MACT, NESHAP	PPPPP, ZZZZ	Applicability Determination for Engine Testing and Emissions Laboratory.

Abstracts

Abstract for [1600009]

Q: Does the EPA approve the use of the same calibration gas to perform quality assurance checks on both the low and the high ranges for a dual range hydrogen sulfide (H2S) continuous emission monitoring system subject to 40 CFR part 60 subpart Ja at the Ergon Refinery in Vicksburg, Mississippi (Ergon)?

A: Yes. Based on the information provided by the Mississippi Department of Environmental Quality (MDEQ), the EPA believes that the Ergon's proposed monitoring alternative is acceptable to satisfy the QA checks on the high concentration range for the Sola II analyzer. EPA's guidance to MDEQ is based upon the expectation that the monitor's higher range will rarely be used to demonstrate compliance because the H2S concentration at the inlet of the Refinery Flare will need to be below the monitor span value to meet the NSPS Ja limits, the highly linear response of the monitor should yield accurate results for the whole range of operation, and the safety hazards to plant employees associated with keeping high concentration H2S calibration gas cylinders onsite being valid concerns due to H2S high toxicity.

Abstract for [1600010]

Q: Does the EPA approve site-specific alternative monitoring operating parameter limits (OPLs) under NSPS subpart Ec for the operation of two hospital/medical/infectious waste incinerators (HMIWI) at the Stericycle Springhill facility located in Sarepta, Louisiana (Stericycle)?

A: Yes. The EPA conditionally approves Stericycle's alternative OPLs, which are consistent with the permit conditions, the equipment configuration of the incinerators, and the operation of the associated air pollution control devices. EPA approval is contingent on Stericycle's successful completion of performance testing on both HWIMI to demonstrate compliance with NSPS subpart Ec emission limits. Stericycle shall conduct a performance test on each HMIWI in accordance with 40 CFR 60.8 and consistent with the proposed performance test plan included in the EPA response letter. If performance testing shows that the facility is not in compliance with NSPS Ee emission limits, retesting will be required, and the OPLs established for this petition approval may require modification, and in the event that new or modified OPLs must be established, a revised OPL petition must be submitted prior to retesting, along with a revised test plan for review and approval.

Abstract for [1600011]

Q: Does EPA approve the revision of alternative Operating Parameter Limits (OPLs) for additional control equipment used in lieu of a wet scrubber at a contraband incinerator operated by SW Border Incineration LLC, in McAllen,

Texas, which meets the criteria of an Other Solid Waste Incinerator (OSWI) unit under NSPS subpart EEEE?

A: Yes. The EPA approves the revision of alternative OPLs contingent on the successful completion of performance testing to demonstrate compliance with NSPS subpart EEEE emission limits. The previously approved and additional OPLs are consistent with the special conditions of Texas Air Permit, which the Texas Commission on Environmental Quality approved the test plan, along with the RATA protocols. If performance testing shows that the facility is not in compliance with NSPS EEEE emission limits, retesting will be required, and the OPLs established for this petition approval may require modification. If additional new or modified OPLs must be established to achieve and maintain compliance with NSPS EEEE, a revised OPL petition must be submitted prior to retesting, along with a revised test plan for review and approval.

Abstract for [1600012]

Q: Does the EPA approve an Alternative Monitoring Plan (AMP) in lieu of using a continuous emission monitoring system (CMS) for Event Corporation to monitor Hydrogen Sulfide (H_2S) during tank degassing and similar operations controlled by a portable temporary thermal oxidizer subject to NSPS subpart J and NSPS subpart Ja at refineries located in the EPA Region 3?

A: Yes. The EPA conditionally approves the AMP since installing and operating an H_2S CMS would be technically impractical due to the short term nature of tank degassing and similar operations performed by Event at refineries located in EPA Region 3. EPA included the detailed AMP sampling steps and compliance demonstration procedures and conditions in the EPA final determination letter.

Abstract for [1600013]

Q: Does the EPA approve an Alternative Monitoring Plan (AMP) in lieu of using continuous emission monitoring system (CMS) for TriStar Global Energy Solution (Tristar) to monitor hydrogen sulfide (H_2S) during tank degassing and similar operations controlled by portable temporary thermal oxidizer units subject to NSPS subpart J and NSPS subpart Ja, at refineries located in EPA Region 3?

A: Yes. The EPA conditionally approves the AMP since installing and operating an H2S continuous emission monitoring system would be technically impractical due to the short term nature of tank degassing and similar operations performed by Tristar at refineries in EPA Region 3. The EPA included the AMP detailed sampling steps, the compliance demonstration procedures and conditions in the final determination letter.

Abstract for [1600018]

Q: Does the EPA determine that the proposed addition of a biodiesel manufacturing facility at a plant owned by Patriot Renewable Fuels (Patriot) and located in Annawan, Illinois is subject to 40 CFR part 60 subpart RRR (VOC Emissions from Synthetic Organic Chemical Manufacturing Industry (SOCMI) Reactor Processes)?

A: Yes. Based on the information provided by the Illinois Environmental Protection Agency (Illinois EPA), the EPA believes that the proposed addition to the biodiesel plant would meet the applicability criteria of subpart RRR. Glycerol, is a chemical listed in 40 CFR 60.707. The EPA considers either of the following downstream uses as indicative of the production of a listed chemical as a ''product'': (1) Production for sale of a listed chemical; or (2) use in another process where that listed chemical is needed. Glycerol is produced from com oil via a hydrolysis reaction during the manufacture of biodiesel. When sent to the fermenters, glycerol is used to increase the ethanol yield (*i.e.,* it is needed in the process) and is, therefore, an intermediate (*i.e.,* a compound that is produced for the use in the production of other compounds or chemicals) under 40 CFR 60.700. Because the glycerol sent to the fermenters is an intermediate, the glycerol is a product. Therefore, our guidance to Illinois EPA is that the Patriot facility would be considered an affected facility subject to Subpart RRR after the addition of the proposed biodiesel plant.

Abstract for [1600027]

Q: Does the EPA approve an alternative monitoring plan (AMP) to use alternative concentrations of span gases used to check daily calibration drift, and as high range validation standards used during cylinder gas audits (CGAs) and relative accuracy test audits (RATAs), under NSPS subpart A for the No. 2 flare Continuous Emission Monitoring System (CEMS) at the Delek Refining (Delek) facility located in Tyler, Texas and covered under NSPS subpart Ja?

A: Yes. Based on the process data and detector information submitted, the EPA conditionally approves Delek's AMP to reduce the concentrations of the calibration gas and validation standards to certain specified range values on the No. 2 Flare CEMS. Delek must conduct linearity analysis on the pulsed ultraviolet fluorescence (PUVF) detector once every three years to determine the detector's linearity across the entire range of expected concentrations of gas vent streams. The analysis must demonstrate that linearity is maintained for the specified vent gas stream hydrogen sulfide (H2S) concentration range. A report of each completed linearity analysis must be submitted to the EPA Region 6 and to the State, and records must be maintained on-site.

Abstract for [1600028]

Q: Does the EPA approve revised process parameter limits for a previously approved Alternative Monitoring Plan (AMP) for the Valero Refining-Texas, LP facility (Valero) located in Corpus Christi, Texas and subject to NSPS subpart J?

A: Yes. The EPA conditionally approves revised process parameter limits that should not exceed the new upper value for total sulfur and the higher proposed temperature. Valero must continue to follow the steps outlined in the previously approved AMP for monitoring the vent stream. If refinery operations change such that the sulfur content of the vent stream changes from representations made for the AMP, then Valero must document the changes and follow the appropriate steps outlined in 40 CFR 60.105(b)(3)(i)–(iii).

Abstract for [1600029]

Q: Does the EPA conditionally approve revised alternative monitoring Operating Parameter Limits (OPLs) for a pollution control system on a new medical waste incinerator subject to NSPS subpart Ec, which consists of a wet gas scrubber (WGS) followed by a carbon adsorber and cartridge filter, located at the University of Texas Medical Branch (UTMBG) in Galveston, Texas?

A: Yes. Based on process-specific information and data provided by UTMBG, the EPA conditionally approves the revised operating parameters for the WGS, carbon adsorber and cartridge filter. UTMBG must conduct a second representative performance test in order to establish revised numerical limits for the operating parameters conditionally approved. The follow up performance testing must be conducted in accordance with 40 CFR 60.8 and State requirements, with no deviations from the EPA-approved test methods or quality assurance protocols. Other OPLs specified by Table 3 of NSPS subpart Ec

and the facility's minor source air permit also must be included in the performance test if the changes affect those pollutants or operating limits. If performance testing shows that the facility is not in compliance with NSPS Ec emission limits, retesting will be required, and the OPLs established for this petition approval may require modification. If additional new or modified OPLs must be established to achieve and maintain compliance with NSPS Ee, a revised OPL petition must be submitted prior to retesting, along with a revised test plan for review and approval.

Abstract for [1600030]

Q: Does the EPA approve the withdrawal of a previously approved Alternative Monitoring Plan (AMP) for a sulfur loading vent stream at the Valero Mckee Refinery located in Sunray, Texas and covered under NSPS subpart J?

A: Yes. The EPA approves the AMP withdrawal of a previously approved AMP because emissions from the tail gas incinerators are monitored for compliance with the sulfur dioxide (SO_2) limit of 40 CFR 60. 104(a)(2)(i) via a continuous emissions monitoring system (CEMS), in accordance with 60.105(a)(3) of NSPS J, as modified on June, 24, 2008, and is consistent with the requirements of Paragraph 226 of the consent decree.

Abstract for [1600031]

Q: Does the EPA approve revisions to an Alternative Monitoring Plan (AMP) that was previously conditionally approved for re-routing a refinery fuel gas vent stream to an alternate combustion device at the Valero Refining-Meraux LLC (Valero Meraux) facility located in Meraux, Louisiana subject to NSPS subpart J?

A: Yes. The EPA approves the revisions to a previously conditionally approved AMP. Valero Meraux proposed re-routing the affected refinery fuel gas vent gas stream to a reformer recharge heater instead of combusting the stream at a stripper reboiler heater. Valero Meraux is required to continue monitoring and controlling the relevant process parameters as summarized in the EPA's previous conditional AMP approval. If refinery operations change such that the sulfur content of the vent stream changes from representations made for the AMP, then Valero must document the changes and follow the appropriate steps outlined in 40 CFR 60. 105(b)(3)(i)–(iii).

Abstract for [1600032]

Q: Does the EPA approve the Alternative Monitoring Plan (AMP) to use the data obtained from the total sulfur (TS) continuous emissions monitoring system (CEMS) for one flare at plant 1 and one flare at plant 2 at the Suncor Energy (USA) Inc. (Suncor) Commerce City Refinery in Commerce City, Colorado subject to NSPS subpart Ja?

A: Yes. The EPA approves Suncor's AMP for flares at plants 1 and 2, pursuant to 40 CFR 60.13(i), to use the data obtained from the TS CEMS low range two-point daily calibration drift and two-point quarterly audits, as well as a one-point challenge in the high range. Because Suncor is requesting this AMP based on a significant safety hazard to refinery personnel and because this monitoring is being performed to detect the threshold for a root cause analysis, not to monitor for compliance with an emission limit, the EPA will allow for minimal use of high concentration calibration gases. This approach avoids routine use of higher level calibration gases in the field; higher level gases are only used for quarterly audits and annual testing and could be brought on-site by a testing contractor and then removed after the test/audit.

Abstract for [1600033]

Q: Does the EPA approve the Alternative Monitoring Plan (AMP) to use the data obtained from the total sulfur (TS) continuous emissions monitoring system (CEMS) for a flare at plant 3 of the Suncor Energy (USA) Inc. (Suncor) Commerce City Refinery in Commerce City, Colorado subject to NSPS subpart Ja?

A: Yes. The EPA approves Suncor's AMP for a flare at plant 3, pursuant to 40 CFR. 40 CFR 60.13(i), to use the data obtained from the TS CEMS low range two-point daily calibration drift and two-point quarterly audits, as well as a one-point challenge in the high range. Because Suncor is requesting this AMP based on a significant safety hazard to refinery personnel and because this monitoring is being performed to detect the threshold for a root cause analysis, not to monitor for compliance with an emission limit, the EPA will allow for minimal use of high concentration calibration gases. This approach avoids routine use of higher level calibration gases in the field; higher level gases are only used for quarterly audits and annual testing and could be brought on-site by a testing contractor and then removed after the test/audit.

Abstract for [1600034]

Q: Does the EPA approve an Alternative Monitoring Plan (AMP) under 40 CFR 60.13(i) for the monitoring of emissions using an emission factor to determine NOx emissions from two stationary gas combustion turbines located at the Power House (Plant) operated by the University of Colorado Boulder (UCB) in Boulder, Colorado, in lieu of determining emissions through Continuous Emissions Monitoring System (CEMS) installed on the bypass stack, to demonstrate compliance with the emission limit under NSPS subpart GG?

A: Yes. Based on the most recent stack testing for NOx emissions during startup of turbine 1 and turbine 2, the EPA will allow UCB use of the 0.32 lb/MMBtu emission factor rather than determining emissions through CEMS installed on the bypass stack. The use of this emission factor provides a conservative emissions estimate and is consistent with UCB permit issued by the Colorado Department of Health and Environment (CDPHE) Air Pollution Control Division (APCD). The EPA or CDPHE APCD may require UCB to conduct additional testing of emissions at the bypass stack to verify the NOx concentrations during turbine startup.

Abstract for [1600035]

Q: Does the EPA approve waiver of a performance testing requirement for six identical stationary engines subject to 40 CFR part 60 subpart JJJJ at the Bio Town Ag facility in Reynolds, Indiana (Bio Town)?

A: Yes. Based on the information Bio Town provided, the EPA approves the performance test waiver request for six identical stationary engines operated in the same manner, pursuant to 40 CFR 60.8(b)(4). Specifically, EPA approves conducting a performance test every 8,760 hours or 3 years, whichever comes first, for the three engines that were constructed in 2011, and a performance test for the three engines that were constructed in 2014, in a staggered schedule as provided in the determination letter. Bio Town must meet Section VII. 2 of the April 27, 2009, Clean Air Act National Stack Testing Guidance, which lists the conditions that must be met for approval of a performance test waiver for identical emissions units.

Abstract for [1600036]

Q: Does the EPA approve the use of a bag leak detection system (BLDS) as an alternative monitoring method in lieu of a continuous opacity monitoring system

(COMS) for purposes of meeting the monitoring requirements under 40 CFR part 60 subpart UUU, Standards of Performance for Calciners and Dryers in Mineral Industries, at the Waupaca Foundry, Inc. plant (Waupaca) located in Tell City, Indiana?

A: Yes. The EPA conditionally approves the Waupaca alternative monitoring method to use BLDS in lieu of a COMS or conducting daily Method 9 readings for the mechanical and thermal sand reclamation unit (P27) being installed at Waupaca's Plant 5. Waupaca will need to develop and prepare a site-specific monitoring plan for the BLDS installed under this alternative monitoring method and meet the conditions specified in the EPA response letter. In addition, Waupaca will need to revise its current major source construction permit for the sand reclamation project, as well as its Title V permit, to incorporate this alternative monitoring method. The approval of the proposed alternative monitoring method does not alter Waupaca's legal obligation to comply with all other applicable requirements associated with Subparts A and UUU, including meeting the opacity limit.

Abstract for [1600037]

Q1: Does the EPA determine the start-up date of Northern Industrial Sand's (NIS) sand dryer located in Auburn, Wisconsin and subject to 40 CFR part 60 subpart UUU is the date the construction permit was issued (June 18, 2015), or the date the sand dryer first processed sand (July 17, 2015)?

A1: The EPA determines that the initial start-up of NIS's sand dryer in question is July 17, 2015. ''Start-up'' is defined at 40 CFR 60. 2 as the setting in operation of an ''affected facility'' for any purpose. Based on the information provided in your letter, the sand dryer at NIS first processed sand on July 17, 2015.

Q2: For purposes of initial performance testing, does the EPA determine that the ''180 days after start-up'' requirement is based on consecutive days (including non-operational days) or operating days?

A2: The EPA determines that the 180 days after start-up requirement is based on calendar days, not operating days. The General Provisions, at 40 CFR 60. 19(a), state ''For the purposes of this part, time periods specified in days shall be measured in calendar days, even if the word 'calendar' is absent, unless otherwise specified in an applicable requirement.'' Neither the General Provisions, at 40 CFR60. 8, nor the requirements of performance testing under subpart UUU, at 40 CFR 60.732 and 60.736, define the time periods for performance testing as anything other than ''days''.

Q3: Does the EPA recommend any other options for NIS to consider for initial performance testing under subpart UUU before the 180-day deadline expires?

A3: Yes. The EPA suggests two testing options. Option 1: NIS may conduct initial performance testing of the sand dryer at its desired maximum throughput and store the processed sand until needed. Based on the information provided, NIS has more than adequate storage capacity for the processed sand to test under this option. Option 2: NIS may conduct performance testing of the sand dryer at less than its desired maximum throughput. However, if this option is selected, NIS will need to take operational restrictions to the reduced throughput at which it tested to show compliance with subpart UUU. The operational restrictions will need to be incorporated into a federally enforceable document (typically a federally enforceable construction or operating permit). If, at a later date, NIS is able to operate at an increased throughput and desires to operate at that increased throughput, it will need to revise its underlying federally enforceable document to accommodate the increased throughput. NIS will also be required to conduct another performance test at that increased rate and demonstrate compliance with applicable limits.

Q4: What does the EPA determine are the monitoring requirements following initial performance testing for the sand dryer?

A4: Based on the information NIS provided, the EPA determines that the sand dryer is an industrial sand fluid bed dryer. The monitoring requirements are therefore either: (a) Installation and operation of a continuous opacity monitoring system (COMS), or (b) daily visible emission readings using U. S. EPA Reference Method 9 (for no less than 18 minutes each day). The monitoring requirements of subpart UUU are found at 40 CFR 60.734(a-d).

Abstract for [1600038]

Q1: Does EPA approve three alternative calibration methods for the total reduced sulfur (TRS) analyzers associated with three flares that are affected facilities under 40 CFR part 60 subpart Ja at the Lima Refining Company (Lima Refining) refinery in Lima, Ohio?

A1: Based on the information provided by Lima Refining, EPA approves two of the three alternative calibration methods requested for the TRS monitors to address safety concerns involving storage, handling, and life expectancy (short expiration dates) of high hydrogen sulfide (H_2S) concentration gas cylinders on site. The two conditional approved calibration methods are: (1) The use of low H2S concentration cylinders to calibrate TRS monitors provided that laboratory analyses demonstrate the linearity of the instruments for the target compound used across the entire sulfur concentration range expected; and (2) the use of a sample dilution system in conjunction with the TRS monitoring systems being installed provided that the dilution system can be challenged at the ratio Lima Refining intends to use, and the capability of the analyzer to detect the lowest expected concentrations of the target compound(s) under typical operating conditions when the gas is diluted at the dilution ratio selected. EPA is disapproving the use of a surrogate gas to calibrate the TRS monitoring systems. This disapproval is based on the fact that the monitoring requirements of subpart Ja are TRS specific. Approvable calibration methodologies should be based on pollutant specific monitoring, when such options are available, rather than a surrogate gas. Since there are feasible pollutant specific options, EPA disapproves the use of a surrogate gas to calibrate the TRS monitors.

Q2: Does EPA approve single point calibrations for each of the TRS analyzers associated with three flares that are affected facilities under subpart Ja?

A2: Yes. EPA approves Lima Refining's request to use single point calibrations for the daily calibration requirements (zero and one other target compound(s) concentration). However, Lima Refining must conduct multi-point calibrations on at least a quarterly basis. Other conditions and requirements of this approval are included in the EPA response letter.

Q3: Does EPA approve a reduced span to that required by subpart Ja for the TRS analyzer associated with the aromatics flare that is an affected facility under subpart Ja?

A3: Yes. EPA conditionally approves Lima Refining's request to reduce the instrument span from 5,000 ppm to 1,000 ppm for the aromatics flare (LIU flare) TRS monitoring system. This approval is based on the low expected TRS concentration from the aromatics flare. However, if readings associated with the aromatics flare exceed 1,000 ppm, then Lima Refining will need to re-span the TRS monitor to a higher value which includes the higher concentration measured.

Abstract for [1600039]

Q: Does EPA approve the use of daily visible emission observations and baghouse pressure drop readings associated with the thermal sand reclamation unit in lieu of a continuous opacity monitoring system (COMS) to meet the monitoring requirements of 40 CFR subpart UUU (Standards of Performance for Calciners and Dryers in Mineral Industries) at the Urschel Laboratories, Inc. (Urschel) in Valparaiso, IN?

A: Yes. EPA conditionally approves the alternative monitoring method to meet the monitoring requirements of subpart UUU at 40 CFR 60.734. Urschel will need to evaluate and establish an appropriate range for the pressure drop across the baghouse based on a performance test at the thermal sand reclamation unit to ensure compliance with subpart UUU. The alternative monitoring program and associated recordkeeping and reporting approved through this letter must be incorporated into its federal enforceable state operating permit. Additional conditions and requirements of this approval are included in the EPA response letter.

Abstract for [1600040]

Q: Does EPA determine that the Urschel Laboratories, Inc. (Urschel) thermal sand reclamation unit located in Valparaiso, Indiana is exempt from the opacity monitoring requirements of 40 CFR part 60 subpart UUU (Standards of Performance for Calciners and Dryers in Mineral Industries) since its particulate emissions are well below 11 tons per year?

A: No. EPA determines that Urschel's thermal sand reclamation unit is an affected facility subject to subpart UUU and is therefore subject to the monitoring requirements at 40 CFR 60.734. Since the thermal sand reclamation unit is not one of the listed facilities under 40 CFR 60.734(b) or (c) and does not use a wet control device (40 CFR 60.734(d)), Urschel must install and operate a continuous opacity monitoring system (COMS). However, the General Provisions at 40 CFR 60.13(i) provides an owner or operator of an affected facility the ability to request, among other things, alternative monitoring to that required by an applicable subpart.

Abstract for [1600041]

Q: Does the EPA approve using an alternative test method ASTM D–6348–12 in lieu of ASTM D–6348–03 for measuring pollutants in the engine exhaust per NSPS subpart JJJJ at Samson Resources Company's facilities on the Southern Ute Indian Reservation in La Plata County, Colorado?

A: Yes. The EPA approves the use of the updated ASTM method, D–6348–12 in lieu of D–6348–03 as prescribed in Table 2 to NSPS JJJJ for performance testing of engines at the requested facilities, pursuant to 40 CFR 60.8(b)(2).

Abstract for [A160001]

Q1: Does the EPA approve a waiver from asbestos testing requirements for bare concrete deck bridges under 40 CFR part 61, subpart M (Asbestos NESHAP), for the Kansas Department of Transportation?

A1: No. Under the Asbestos NESHAP, there is no regulatory provision that allows the EPA to issue a waiver.

Q2: Does the EPA determine that bare concrete deck bridges are subject to the Asbestos NESHAP regulation?

A2: Yes. The EPA determines that concrete is considered a building material and needs to be evaluated for asbestos-content. At a minimum, it must be thoroughly inspected.

Abstract for [A160002]

Q1: Does the EPA determine that airport taxiways are subject to 40 CFR part 61, subpart M (Asbestos NESHAP)?

A1: Yes. The EPA indicated to the Missouri Department of Natural Resources (MO DNR) that airport taxiways are a ''facility component'' as defined in 40 CFR 61.141 and therefore subject to the regulation. At a minimum, the taxiway is subject to the thorough inspection requirement of the regulation. Further, MO DNR asks that EPA reconsider a previous applicability determination which stated airport runways were not subject to the Asbestos NESHAP. This applicability determination supersedes the June 20, 1997 applicability determination with ADI Control No. A970006.

Q2: Does the EPA determine that repair operations on a taxiway are considered a renovation or demolition operation under the Asbestos NESHAP regulation?

A2: Yes. The EPA determines if work is to be done on an airport taxiway, it is considered a renovation operation as there is no load-supporting structural member being wrecked or taken out as defined under the demolition definition.

Abstract for [M160005]

Q: Does EPA determine that McConway and Torley's Lawrenceville Foundry in Pittsburgh, Pennsylvania is subject to 40 CFR part 63 subpart XXXXXX (subpart 6X), NESHAP for Nine Metal Fabrication and Finishing Source Categories?

A: No. EPA has determined that subpart 6X does not apply to the Lawrenceville Foundry based on not meeting rule applicability requirements due to current operations, an evaluation of the SIC/NAICS codes associated with the facility, and the corresponding activities in which the facility is primarily engaged in that involves manufacturing of railroad car couplings.

Abstract for [M160007]

Q1: Does EPA determine that the raw material used by Mica Company of Canada Incorporated (Mica Co.) at their Newport News, Virginia facility meets the definition of a ''web'' and that both manufacturing lines are subject to 40 CFR part 63 subpart JJJJ?

A1: Based on the description provided by Mica Co., EPA determines that the raw material used by Mica Co. processing line 2 meets the definition of a ''web'' at 40 CFR 63.3300 since the mica paper is fed from a roll to the web coating line. Therefore, this processing line is subject to MACT subpart JJJJ. Processing line 1 does not meet the definition of web and is therefore not subject to MACT subpart JJJJ.

Q2: Does EPA determine that the end products manufactured by Mica Co. meet the definition of a ''refractory product'' and that both processing lines are therefore subject to 40 CFR part 63 subpart SSSSS?

A2: No. Based on the description provided by Mica Co., EPA determines that the mica sheet insulating products manufactured by Mica Co. do not meet the definition of a ''refractory product'' at 40 CFR 63.9824; therefore, the manufacturing lines are not subject to MACT subpart SSSSS.

Abstract for [M160009]

Q: Does EPA determine that the Teva Pharmaceuticals USA, Inc. Women's Health pharmaceutical manufacturing facility in Cincinnati, Ohio (Teva) is subject to the NESHAP subpart VVVVVV Title V Permit requirement if the facility took operational limits on organic compounds to become an area source before the effective date of the rule and now operate control devices, but would still be an area source without the controls?

A: No. EPA determines that the Teva pharmaceutical manufacturing operations at the Cincinnati facility are not currently subject to the Title V requirement in NESHAP subpart VVVVVV. Since the facility took operational limits to obtain area source status prior to the effective date of the rule, the Title V NESHAP subpart VVVVVV requirement does not apply, even if it now operates controls. The

facility does not rely on a control device to maintain HAP emissions below major source thresholds as was demonstrated with the potential to emit analysis.

Abstract for [M160017]

Q: Does EPA determine that the Owens Corning Insulating Systems, LLC (OC) a wool fiberglass products manufacturing plant located in Delmar, NY (Delmar), is subject to 40 CFR part 63 subpart JJJJ, NESHAP for Paper and Other Web Coating Manufacturing?

A: Yes. Based on the information provided by OC, EPA determines that the Delmar plant still operates web coating lines after switching from a phenol-formaldehyde binder to a starch binder and thus remains subject to 40 CFR part 63 subpart JJJJ, and that the subsequent non applicability determination for 40 CFR part 63 subpart NNN, the NESHAP for Wool Fiberglass Manufacturing due to the binder switch is irrelevant to the applicability status of 40 CFR part 63 subpart JJJJ. This determination is consistent with the ''Once-In-Always-In'' policy. The Delmar plant has been required to comply with subpart JJJJ provisions (including emissions standards) since December 5, 2005, the first substantive compliance date of rule, based on 40 CFR 63.320(a) of the rule. The fact that OC chooses to comply with the subpart JJJJ emission standards at the Delmar plant using a method it was already using (*i.e.,* the ''[u]se of 'as-purchased' compliant coating materials'') prior to the first substantive compliance date is irrelevant to the applicability analysis.

Abstract for [M160019]

Q: Does EPA approve an Alternative Monitoring Plan (AMP) for a Wet Gas Scrubber (WGS) on a Fluidized Catalytic Cracking Unit (FCCU) subject to NSPS part 60 subpart J, and also NESHAP subpart UUU, for parametric monitoring of opacity at the WGS in lieu of a Continuous Opacity Monitoring System, due to moisture interference on opacity readings in the stack at the Valero Refining Company (Valero) facility in Ardmore, Oklahoma (Valero)?

A: Yes. Based upon the design of the WGS unit and the process specific information and performance test results provided by Valero, EPA approves the AMP request and its operating parameter limits (OPLs) for demonstrating compliance under NESHAP subpart UUU, which included minimum Liquid-to-Gas Ratio, minimum water pressure to the quench/spray tower nozzles, and minimum pressure drop across the Agglo-filtering module. Valero shall incorporate the terms of this AMP approval into the facility's New Source Review (NSR) and Title V permits for federal enforceability. If refinery operations change, Valero shall conduct another performance test to establish new limits for the OPLs listed in the EPA response letter.

Abstract for [M160020]

Q: Does EPA determine that the Ervin Amasteel facility in Adrian, Michigan should be classified as a steel foundry subject to requirements of the NESHAP for Iron and Steel Foundries Area Source, at 40 CFR part 63 subpart ZZZZZ, and not the requirements under the NESHAP for Area Sources for Electric Arc Furnace Steelmaking Facilities, at 40 CFR part 63 subpart YYYYY, and the Standards of Performance for Steel Plants: Electric Arc Furnaces and Argon-Oxygen Decarburization Vessels Constructed After August 17, 1983, at 40 CFR part 60 Subpart AAa (NSPS AAa)?

A: No. EPA determines that the Ervin Amasteel facility is not subject to the requirements of NESHAP subpart ZZZZZ because the facility is not an iron and steel foundry as defined in 40 CFR 63.10906 of the rule. Therefore, the Ervin Amasteel facility remains subject to the applicable provisions of NESHAP subpart YYYYY and NSPS subpart AAa.

Abstract for [M160021]

Q: Does EPA approve an alternative monitoring method for the bypass valve line associated with the thermal oxidizer in lieu of a continuous flow monitor or securing the bypass valve with a car seal or lock-and-key type system to meet the monitoring requirements of 40 CFR part 63 subpart JJJ at the INEOS Barex USA LLC (INEOS) plant in Lima, Ohio?

A: Yes. Based on the information provided by INEOS, including concerns about installation of a flow monitor on this particular bypass stream due to location and corrosion possibilities, EPA conditionally approves the alternative monitoring method that requires continuous monitoring of the bypass valve position associated with the thermal oxidizer in accordance with 40 CFR 63.8(f)(2) and (4). The recordkeeping and reporting conditions for approval are specified in the EPA response letter.

Abstract for [Z160005]

Q1: Does EPA determine that stationary engines being tested in a test cell at Maine Maritime Academy (MMA) in Castine, Maine would be subject to the NESHAP for Reciprocating Internal Combustion Engines (RICE), 40 CFR part 63 subpart ZZZZ?

A1: No. EPA determines that because the engines in question will be tested at a stationary RICE test cell as defined in Subpart PPPPP, they are not subject to subpart ZZZZ consistent with 40 CFR 63.6675 of subpart ZZZZ.

Q2: Does EPA determine that the proposed engine test cell at MMA, which is an area source of hazardous air pollutants, would be subject to the NESHAP for Engine Test Cell/Stands, 40 CFR part 63 subpart PPPPP?

A2: No. EPA determines that as long as MMA remains an area source of hazardous air pollutants (HAPs), it is not subject to subpart PPPPP, which applies to owners or operators of engine test cells/stands at a major source of HAPs.

Dated: July 20, 2017.

David A. Hindin,

Director, Office of Compliance, Office of Enforcement and Compliance Assurance.

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ENVIRONMENTAL PROTECTION AGENCY

[ER–FRL–9034–5]

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 07/24/2017 Through 07/28/2017
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. 20170143, Final, FHWA, UT, I–80 and State Street Interchange, *Contact:* Brandon Weston, 801–965–4603.

Under MAP–21 Section 1319, FHWA has issued a single FEIS and ROD. Therefore, the 30-day wait/review period under NEPA does not apply to this action.

EIS No. 20170144, Final Supplement, BOEM, MA, Cape Wind Energy Project, *Review Period Ends:* 09/05/2017, *Contact:* Michelle Morin 703–787–1722.

EIS No. 20170145, Final, NSF, PR, Arecibo Observatory, *Review Period*

Ends: 09/05/2017, *Contact:* Elizabeth Pentecost 703–292–4907.

EIS No. 20170146, Draft, USAF, AK, Air Force Proposal to Improve F–22 Operational Efficiency at Joint Base Elmendorf-Richardson (JBER), Alaska, *Comment Period Ends:* 09/18/2017, *Contact:* JBER Public Affairs 907–552–8151.

EIS No. 20170147, Final, USFS, CA, Trestle Forest Health Project, *Review Period Ends:* 09/05/2017, *Contact:* Jennifer Marsolais 530–642–5187.

EIS No. 20170148, Final, FERC, WV, Mountaineer Xpress and Gulf XPress Projects, *Review Period Ends:* 09/05/2017, *Contact:* Julia Yuan 202–502–8130.

EIS No. 20170149, Final, BOEM, LA, Geological and Geophysical Activities on the Gulf of Mexico Outer Continental Shelf, *Review Period Ends:* 09/05/2017, *Contact:* Terri Thomas 504–736–2963.

Dated: August 1, 2017.

Dawn Roberts,

Management Analyst, NEPA Compliance Division, Office of Federal Activities.

[FR Doc. 2017–16479 Filed 8–3–17; 8:45 am]

BILLING CODE 6560–50–P

EXPORT-IMPORT BANK

[Public Notice: 2017–6004]

Agency Information Collection Activities: Comment Request for Form EIB 11–01, Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery

AGENCY: Export-Import Bank of the United States.

ACTION: Submission for OMB review and comments request.

SUMMARY: The proposed clearance is designed to allow Ex-Im Bank to survey for the purpose of gaining insights into customers' experiences with the agency and to evaluate product and performance effectiveness. Customers' responses will help to identify potential areas of service improvement and rate overall program experiences.

DATES: Comments must be received on or before September 5, 2017 to be assured of consideration.

ADDRESSES: Comments may be submitted electronically on *www.regulations.gov* or by mail to Mardel West, Export-Import Bank of the United States, 811 Vermont Ave. NW., Washington, DC 20571.

SUPPLEMENTARY INFORMATION:

Affected Public: Individuals representing companies engaged in business with the Export-Import Bank of the U.S.

Burden Hours

Annual Number of Respondents: 3200.

Estimated Time per Respondent: 45 minutes.

Annual Public Burden Hours: 2400 hours.

Frequency of Reporting of Use: On occasion.

Government Expense

Reviewing Time per year: 1,600 Hours.

Average Wages per Hour: $42.50.

Average Cost per Year: $68,000.

Benefits and Overhead: 20%.

Total government Cost: $81,600.

Bassam Doughman,

Project Manager, Export-Import Bank of the United States.

[FR Doc. 2017–16103 Filed 8–3–17; 8:45 am]

BILLING CODE 6690–01–P

EXPORT-IMPORT BANK

[Public Notice: 2017–6005]

Agency Information Collection Activities: Comment Request on Form EIB 10–04 Notice of Claim and Proof of Loss, Working Capital Guarantee

AGENCY: Export-Import Bank of the United States.

ACTION: Submission for OMB review and comments request.

SUMMARY: The Export-Import Bank of the United States (Ex-Im Bank), as 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.

DATES: Comments must be received on or before September 5, 2017 to be assured of consideration.

ADDRESSES: Comments may be submitted electronically on *www.regulations.gov* or by mail to Mardel West, Export-Import Bank of the United States, 811 Vermont Ave. NW., Washington, DC 20571.

SUPPLEMENTARY INFORMATION: By neutralizing the effect of export credit support offered by foreign governments and by absorbing credit risks that the private sector will not accept, Ex-Im Bank enables U.S. exporters to compete fairly in foreign markets on the basis of price and product. Under the Working Capital Guarantee Program, Ex-Im Bank provides repayment guarantees to lenders on secured, short-term working capital loans made to qualified exporters. The guarantee may be approved for a single loan or a revolving line of credit. In the event that a borrower defaults on a transaction guaranteed by Ex-Im Bank the guaranteed lender may seek payment by the submission of a claim.

This collection of information is necessary, pursuant to 12 U.S.C. 635(a)(1), to determine if such claim complies with the terms and conditions of the relevant working capital guarantee. The Notice of Claim and Proof of Loss, Working Capital Guarantee is used to determine compliance with the terms of the guarantee and the appropriateness of paying a claim. Export-Import Bank customers are able to submit this form on paper or electronically.

The information collection tool can be reviewed at: *http://www.exim.gov/pub/pending/eib10-04.pdf.*

Title and Form Number: EIB 10–04 Notice of Claim and Proof of Loss, Working Capital Guarantee.

OMB Number: 3048–0035.

Type of Review: Regular.

Need and Use: This collection of information is necessary, pursuant to 12 U.S.C. 635(a)(1), to determine if such claim complies with the terms and conditions of the relevant guarantee.

Affected Public: This form affects entities involved in the export of U.S. goods and services.

Annual Number of Respondents: 17.

Estimated Time per Respondent: 1 hour.

Annual Burden Hours: 17 hours.

Frequency of Reporting of Use: As needed to request a claim payment.

Government Expenses:

Reviewing time per year: 17 hours.

Average Wages per Hour: $42.50.

Average Cost per Year: $722.50 (time*wages).

Benefits and Overhead: 20%.

Total Government Cost: $867.

Bassam Doughman,

Project Manager, Export-Import Bank of the United States.

[FR Doc. 2017–16102 Filed 8–3–17; 8:45 am]

BILLING CODE 6690–01–P

FEDERAL COMMUNICATIONS COMMISSION

Open Commission Meeting, Thursday, August 3, 2017

July 27, 2017.

The Federal Communications Commission will hold an Open Meeting on the subjects listed below on

Thursday, August 3, 2017 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	Wireline Competition	*Title:* Connect America Fund Phase II Auction (Auction 903), (AU Docket No. 17–182). *Summary:* The Commission will consider a Public Notice to initiate the pre-auction process for the Connect America Fund Phase II auction which will award up to $1.98 billion over 10 years to service providers that commit to offer voice and broadband services to fixed locations in unserved high-cost areas.
2	Wireless Telecommunications	*Title:* Connect America Fund (WC Docket No. 10–90); Universal Service Reform—Mobility Fund (WT Docket No. 10–208). *Summary:* The Commission will consider an Order on Reconsideration and Second Report and Order that lays out a robust challenge process that will enable the Commission to direct Mobility Fund Phase II support to primarily rural areas that lack unsubsidized 4G Long Term Evolution (LTE) service.
3	Wireline Competition	*Title:* Modernizing the FCC Form 477 Data Program (WC Docket No. 11–10). *Summary:* The Commission will consider a Further Notice of Proposed Rulemaking that takes a focused look at the Commission's Form 477 to improve the value of the data we continue to collect.
4	Wireless Telecommunications	*Title:* Expanding Flexible Use in Mid-Band Spectrum Between 3.7 and 24 GHz (GN Docket No. 17–183). *Summary:* The Commission will consider a Notice of Inquiry that explores opportunities for next generation services—particularly for wireless broadband—in the 3.7 GHz to 24 GHz spectrum range and asks about how we can increase efficient and effective use of this spectrum for the benefit of all services and users.
5	Wireless Telecommunications	*Title:* Video Description: Implementation of the Twenty-First Century Communications and Video Accessibility Act of 2010 (MB Docket No. 11–43). *Summary:* The Commission will consider a Report and Order which increases the required hours of video described programming that covered broadcast stations and MVPDs must provide to consumers.
6	International	*Title:* Implementation of Section 25.281(b) Transmitter Identification Requirements for Video Uplink Transmissions (IB Docket No. 12–267). *Summary:* The Commission will consider a Memorandum Opinion and Order that waives the requirement that satellite news trucks, and other temporary-fixed satellite earth stations transmitting digital video, comply with the Digital Video Broadcasting-Carrier Identification (DVB–CID) standard if the earth station uses a modulator that cannot meet the DVB–CID standard through a software upgrade.
7	Media	*Title:* Hearing Designation Order. *Summary:* The Commission will consider a Hearing Designation Order.
8	Enforcement	*Title:* Enforcement Bureau Action. *Summary:* The Commission will consider an enforcement action.
*	* * * * * * *	

Consent Agenda

The Commission will consider the following subject listed below as a consent agenda and this item will not be presented individually:		
1	Enforcement	*Title:* Enforcement Bureau Action. *Summary:* The Commission will consider an enforcement action.

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.

Katura Jackson,

Federal Register Liaison Officer, Office of the Secretary.

[FR Doc. 2017–16474 Filed 8–3–17; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL DEPOSIT INSURANCE CORPORATION

Notice to All Interested Parties of the Termination of the Receivership of 10389—Public Savings Bank, Huntingdon Valley, Pennsylvania

Notice is hereby given that the Federal Deposit Insurance Corporation (''FDIC'')

as Receiver for Public Savings Bank, Huntingdon Valley, Pennsylvania (''the Receiver'') intends to terminate its receivership for said institution. The FDIC was appointed receiver of Public Savings Bank on August 18, 2011. 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, 2017.

Federal Deposit Insurance Corporation.

Robert E. Feldman,

Executive Secretary.

[FR Doc. 2017–16481 Filed 8–3–17; 8:45 am]

BILLING CODE 6714–01–P

GENERAL SERVICES ADMINISTRATION

[Notice–WWICC–2017–02; Docket No. 2017–0003; Sequence 2]

World War One Centennial Commission; Notification of Change to Upcoming Public Advisory Meeting

AGENCY: World War One Centennial Commission.

ACTION: Meeting notice.

SUMMARY: Notice of this meeting is being provided according to the requirements of the Federal Advisory Committee Act. This notice provides the schedule and agenda for the September 13, 2017 meeting of the World War One Centennial Commission (the Commission). The meeting is open to the public.

DATES: *Applicable:* September 13, 2017.

Meeting Date: The meeting will be held on Wednesday, September 13, 2017, starting at 10:00 a.m. Eastern Daylight Saving Time (EDT), and ending no later than 2:00 p.m., EDT. Written Comments may be submitted to the Commission and will be made part of the permanent record of the Commission. Comments must be received by 5:00 p.m., EDT, on September 8, 2017, and may be provided by email to *daniel.dayton@worldwar1centennial.gov*.

Contact Daniel S. Dayton at *daniel.dayton@worldwar1centennial.org* to register to comment during the meeting's 30-minute public comment period. Registered speakers/organizations will be allowed 5 minutes and will need to provide written copies of their presentations. Requests to comment, together with presentations for the meeting must be received by 5:00 p.m. (EDT), on Friday, September 8, 2017. Please contact Mr. Dayton at the email address above to obtain meeting materials.

FOR FURTHER INFORMATION CONTACT: Daniel S. Dayton, Designated Federal Officer, World War 1 Centennial Commission, 701 Pennsylvania Avenue NW., 123, Washington, DC 20004–2608 202–380–0725 (note: this is not a toll-free number).

SUPPLEMENTARY INFORMATION:

Background

The World War One Centennial Commission was established by Public Law 112–272 (as amended), as a commission to ensure a suitable observance of the centennial of World War I, to provide for the designation of memorials to the service of members of the United States Armed Forces in World War I, and for other purposes. Under this authority, the Committee will plan, develop, and execute programs, projects, and activities to commemorate the centennial of World War I, encourage private organizations and State and local governments to organize and participate in activities commemorating the centennial of World War I, facilitate and coordinate activities throughout the United States relating to the centennial of World War I, serve as a clearinghouse for the collection and dissemination of information about events and plans for the centennial of World War I, and develop recommendations for Congress and the President for commemorating the centennial of World War I. The Commission does not have an appropriation and operates on donated funds.

Agenda: Wednesday, September 13, 2017

Old Business

- Acceptance of minutes of last meeting
- Public Comment Period

New Business

- Executive Director's Report—Executive Director Dayton
- Executive Committee Report—Commissioner Hamby
- Financial Committee Report—Vice Chair Fountain
- Memorial Report—Vice Chair Fountain
- Fundraising Report—Commissioner Sedgwick
- Education Report—Dr. O'Connell
- Endorsements—(RFS)—Dr. Seefried
- International Report—Dr. Seefried
- Other Business
- Chairman's Report
- Set Next Meeting—December 13, 2017—PMML, Chicago, IL
- Motion to Adjourn

Dated: August 1, 2017.

Daniel S. Dayton,

Designated Federal Official, World War I Centennial Commission.

[FR Doc. 2017–16466 Filed 8–3–17; 8:45 am]

BILLING CODE 6820–95–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifiers: CMS–381]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Centers for Medicare & Medicaid Services.

ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (the PRA), federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information (including each proposed extension or reinstatement of an existing collection of information) and to allow 60 days for public comment on the proposed action. Interested persons are invited to send comments regarding our burden estimates or any other aspect of this collection of information, including the necessity and utility of the proposed information collection for the proper

performance of the agency's functions, the accuracy of the estimated burden, ways to enhance the quality, utility, and clarity of the information to be collected, and the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments must be received by October 3, 2017.

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: William Parham at (410) 786–4669.

SUPPLEMENTARY INFORMATION:

Contents

This notice sets out a summary of the use and burden associated with the following information collections. More detailed information can be found in each collection's supporting statement and associated materials (see **ADDRESSES**).

CMS–381 Identification of Extension Units of Medicare Approved Outpatient Physical Therapy/Outpatient Speech Pathology (OPT/OSP) Providers and Supporting Regulations

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:* Extension of a currently approved collection; *Title of Information Collection:* Identification of Extension Units of Medicare Approved Outpatient Physical Therapy/Outpatient Speech Pathology (OPT/OSP) Providers and Supporting Regulations; *Use:* The provider uses the form to report to the state survey agency extension locations that it has added since the date of last report. The form is used by the state survey agencies and by our regional offices to identify and monitor extension locations to ensure their compliance with the federal requirements for the providers of outpatient physical therapy and speech-language pathology services. *Form Number:* CMS–381 (OMB control number: 0938–0273); *Frequency:* Annually; *Affected Public:* Private Sector; Business or other for-profit and not-for-profit institutions; *Number of Respondents:* 2,161; *Total Annual Responses:* 2,161; *Total Annual Hours:* 540. (For policy questions regarding this collection contact Sarah Fahrendorf at 410–786–3112.)

Dated: August 1, 2017.

William N. Parham, III,

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2017–16483 Filed 8–3–17; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–9104–N]

Medicare and Medicaid Programs; Quarterly Listing of Program Issuances—April through June 2017

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 2017, 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
VI Collections of Information	William Parham	(410) 786–4669
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

Addenda	Contact	Phone number
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 20, 2017.

Kathleen Cantwell,

Director, Office of Strategic Operations and Regulatory Affairs.

BILLING CODE 4120–01–C

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 5, 2016 (81 FR 51901), November 2016 (81 FR 79489, February 23, 2017 (82 FR 11456), and May 5, 2017 (82 FR 21241). 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 2017)

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 Percutaneous Image-guided Lumbar Decompression (PILD) for Lumbar Spinal Stenosis (LSS) use (CMS-Pub. 100-03) Transmittal No. 196.

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)	
104	Affordable Care Act Bundled Payments for Care Improvement Initiative – Recurring File Updates Models 2 and 4 October 2017 Updates
105	Update to General Information, Eligibility, and Entitlement, Chapter 7 – Contract Administrative Requirements, Section 40 – Shared System Maintainer Responsibilities for Systems Releases
Medicare Benefit Policy (CMS-Pub. 100-02)	
235	Removal of Contractor Requirement to Submit Opt Out Data into the Contractor Reporting of Operational and Workload Data (CROWD) System (Form 8)
Medicare National Coverage Determination (CMS-Pub. 100-03)	
195	Screening for Hepatitis B Virus (HBV) Infection
196	Percutaneous Image-guided Lumbar Decompression (PILD) for Lumbar Spinal Stenosis (LSS)
197	Screening for Hepatitis B Virus (HBV) Infection
Medicare Claims Processing (CMS-Pub. 100-04)	
3744	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction

3745	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
3746	July 2017 Quarterly Average Sales Price (ASP) Medicare Part B Drug Pricing Files and Revisions to Prior Quarterly Pricing Files
3747	Payment for Moderate Sedation Services
3748	Quarterly Update to the National Correct Coding Initiative (NCCI) Procedure to Procedure (PTP) Edits, Version 23.2, Effective July 1, 2017
3749	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
3750	New Fields in the Fiscal Intermediary Shared System (FISS) Inpatient and Outpatient Provider Specific Files (PSF)
3751	Two New "K" Codes for Therapeutic Continuous Glucose Monitors
3752	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
3753	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
3754	Implementation of New Influenza Virus Vaccine Code Table of Preventive and Screening Services Healthcare Common Procedure Coding System (HCPCS) and Diagnosis Codes Payment for Pneumococcal Pneumonia Virus, Influenza Virus, and Hepatitis B Virus and Their Administration on Institutional Claims Payment Procedures for Renal Dialysis Facilities (RDF CWF Edits on AB MAC (A) Claims CWF Edits on AB MAC (B) Claims CWF Crossover Edits for AB MAC (B) Claims
3755	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
3756	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
3757	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
3758	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
3759	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
3760	July Quarterly Update for 2017 Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Fee Schedule
3761	Screening for Hepatitis B Virus (HBV) Infection Screening for Hepatitis B Virus (HBV) Institutional Billing Requirements Professional Billing Requirements Diagnosis Code Reporting Requirements Claim Adjustment Reason Codes (CARCs), Remittance Advice Remark Messages
3762	New Physician Specialty Code for Advanced Heart Failure and Transplant Cardiology, Medical Toxicology, and Hematopoietic Cell Transplantation and Cellular Therapy Physician Specialty Codes
3763	Table of Preventive and Screening Services Deductible and Coinsurance
3764	Qualified Medicare Beneficiary Indicator in the Medicare Fee-For-Service Claims Processing System
3765	Modifications to the Common Working File (CWF) In Support of the Coordination of Benefits Agreement (COBA) Crossover Process Claims Crossover Disposition and Coordination of Benefits Agreement By-Pass Indicators
3766	Screening for the Human Immunodeficiency Virus (HIV) Infection Healthcare Common Procedure Coding System (HCPCS) for HIV Screening Tests Billing Requirements Payment Method Diagnosis Code Reporting Medicare Summary Notice (MSN) and Claim Adjustment Reason Codes (CARCs)
3767	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
3768	April Quarterly Update for 2017 Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Fee Schedule
3769	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
3770	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
3771	New Waived Tests
3772	Quarterly Update to the Medicare Physician Fee Schedule Database (MPFSDB) - July CY 2017 Update
3773	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
3774	Changes to the Payment Policies for Reciprocal Billing Arrangements and Fee-For-Time Compensation Arrangements (formerly referred to as Locum Exceptions to Assignment of Provider's Right to Payment)-Claims Submitted to A/B MACs Part B Payment Under Reciprocal Billing Arrangements - Claims Submitted to A/B MACs Part B Payment Under Fee-For-Time Compensation Arrangements (formerly referred to as Locum Tenens Arrangements) - Claims Submitted to A/B MACs Part B Billing Procedures for Entities Qualified to Receive Payment on Basis of Reassignment - for A/B MAC Part B Processed Claims Correcting Unacceptable Payment Arrangements Tenens Arrangements)
3775	Two New "K" Codes for Therapeutic Continuous Glucose Monitors
3776	Issued to a specific audience, not posted to Internet/ Intranet due to Confidentiality of Instruction
3777	July 2017 Integrated Outpatient Code Editor (I/OCE) Specifications Version 18.2
3778	Screening for the Human Immunodeficiency Virus (HIV) Infection Healthcare Common Procedure Coding System (HCPCS) for HIV Screening Tests Billing Requirements Payment Method Diagnosis Code Reporting Medicare Summary Notice (MSN) and Claim Adjustment Reason Codes

	(CARCs)
3779	Instructions to Process Services Not Authorized by the Veterans Administration (VA) in a Non-VA Facility Reported With Value Code (VC) 42 Requirements for Processing Non Veterans Administration (VA) Authorized Inpatient Claims
3780	Remittance Advice Remark Code (RARC), Claims Adjustment Reason Code (CARC), Medicare Remit Easy Print (MREP) and PC Print Update
3781	Implement Operating Rules - Phase III Electronic Remittance Advice (ERA) Electronic Funds Transfer (EFT): CORE 360 Uniform Use of Claim Adjustment Reason Codes (CARC), Remittance Advice Remark Codes (RARC) and Claim Adjustment Group Code (CAGC) Rule – Update from Council for Affordable Quality Healthcare (CAQH) Committee on Operating Rules for Information Exchange (CORE)
3782	Claim Status Category and Claim Status Codes Update
3783	July 2017 Update of the Hospital Outpatient Prospective Payment System (OPPS)
3784	Instructions for Downloading the Medicare ZIP Code File for October Files
3785	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instruction
3786	Common Edits and Enhancements Modules (CEM) Code Set Update
3787	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instruction
3788	July 2017 Update of the Ambulatory Surgical Center (ASC) Payment System
3789	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
3790	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
3791	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
3792	July 2017 Update of the Ambulatory Surgical Center (ASC) Payment System
3793	Screening for Hepatitis B Virus (HBV) Infection Screening for Hepatitis B Virus (HBV) Institutional Billing Requirements Professional Billing Requirements Diagnosis Code Reporting Requirements Claim Adjustment Reason Codes (CARCs), Remittance Advice Remark Codes (RARCs), Group Codes, and Medicare Summary Notice (MSN) Messages
Medicare Secondary Payer (CMS-Pub. 100-05)	
119	Implement the International Classification of Diseases, Tenth Revision (ICD-10) 2018 General Equivalence Mappings (GEMs) Tables in the Common Working File (CWF) for Purposes of Processing Non-Group Health Plan (NGHP) Medicare Secondary Payer (MSP) Records and Claims
Medicare Financial Management (CMS-Pub. 100-06)	
282	Notice of New Interest Rate for Medicare Overpayments and Underpayments -3rd Qtr Notification for FY 2017
283	New Physician Specialty Code for Advanced Heart Failure and Transplant Cardiology, Medical Toxicology, and Hematopoietic Cell Transplantation and

	Cellular Therapy
Medicare State Operations Manual (CMS-Pub. 100-07)	
169	New to State Operations Manual (SOM) Appendix Z, Emergency Preparedness for All Provider and Certified Supplier Types
Medicare Program Integrity (CMS-Pub. 100-08)	
710	Update to Pub. 100-08, Chapter 15 Federally Qualified Health Centers (FQHCs) Section 4 of the Form CMS-855I Submission of Paper and Internet-based PECOS Certification Statements Processing Form CMS-855R Applications Electronic Funds Transfer (EFT) Payments and CHOWs Tie-In/Tie-Out Notices and Referrals to the State/RO Ambulatory Surgical Centers (ASCs)/Portable X-ray Suppliers (PXRS) Tie-In/Tie-Out Notices and Referrals to the State/RO Release of Information File Maintenance Approval Letter Guidance Model Approval Letter Denial Example #5 – Existing or Delinquent Overpayments
711	Update to Pub. 100-08, Chapter 15 Diabetes Self-Management Training (DSMT) Section 4 of the Form CMS-855I Submission of Paper and Internet-based PECOS Certification Statements Processing Form CMS-855R Applications Electronic Funds Transfer (EFT) Payments and CHOWs Tie-In/Tie-Out Notices and Referrals to the State/RO Ambulatory Surgical Centers (ASCs)/Portable X-ray Suppliers (PXRS) Tie-In/Tie-Out Notices and Referrals to the State/RO Release of Information File Maintenance Approval Letter Guidance Model Approval Letter Denial Example #5 – Existing or Delinquent Overpayments
712	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
713	Scribe Services Signature Requirements
714	Comprehensive Error Rate Testing (CERT) File Layout for Social Security Number Removal Initiative (SSNRI)
715	Update to Pub. 100-08, Chapter 15 Federally Qualified Health Centers (FQHCs) Section 4 of the Form CMS-855I Submission of Paper and Internet-based PECOS Certification Statements Processing Form CMS-855R Applications Electronic Funds Transfer (EFT) Payments and CHOWs Tie-In/Tie-Out Notices and Referrals to the State/RO Ambulatory Surgical Centers (ASCs)/Portable X-ray Suppliers (PXRS) Tie-In/Tie-Out Notices and Referrals to the State/RO Release of Information
716	Clarifying Medical Review of Hospital Claims for Part A Payment Medical Review of Hospital Claims for Part A Payment

	Conducting Patient Status Reviews of Claims for Medicare Part A Payment for Inpatient Hospital Admissions
717	Federally Qualified Health Centers (FQHCs) Section 4 of the Form CMS-855I Submission of Paper and Internet-based PECOS Certification Statements Processing Form CMS-855R Applications Electronic Funds Transfer (EFT) Payments and CHOWs Tie-In/Tie-Out Notices and Referrals to the State/RO Ambulatory Surgical Centers (ASCs)/Portable X-ray Suppliers (PXRS) Tie-In/Tie-Out Notices and Referrals to the State/RO Release of Information File Maintenance Model Approval Letter Denial Example #5 – Existing or Delinquent Overpayments
718	Reviewing for Adverse Legal Actions (ALA)
719	Update to Reporting Requirements Reconsideration Requests – Non-certified Providers/Suppliers External Reporting Requirements
720	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
721	Elimination of Routine Reviews Including Documentation Compliance Reviews and Instituting Three Medical Reviews Overview of Prepayment and Postpayment Reviews Provider Notice Requesting Additional Documentation During Prepayment and Postpayment Review Third-party Additional Documentation Request Special Provisions for Lab Additional Documentation Requests No Response or Insufficient Response to Additional Documentation Requests Reopening Claims with Additional Information or Denied due to Late or No Submission of Requested Information Use of Claims History Information in Claim Payment Determinations Types of Review: Medical Record Review, Non-Medical Record Review, and Automated Review Complex Medical Review Non-Complex Review Automated Review Electronic and Paper Claims Prepayment Review of Claims Involving Utilization Parameters Prepayment Medical Record Review Edits Postpayment Medical Record Review of Claims Re-opening Claims Case Selection CMS Mandated Edits Tracking Medicare Contractors' Postpayment Reviews Denial Types Beneficiary Notification Notifying the Provider Corrective Actions
	Evaluation of Prepayment Edits Suppression and/or Exclusion – Examples Workload Medical Review of Home Health Demand Bills Referrals to the Quality Improvement Organization (QIO Medical Review Definitions Definition Automated Medical Review Non-Medical Record Review Automated Medical Review Non-Medical Record Review Prepay Provider Specific Medical Record Review Prepay Service Specific Medical Record Review Prepay Provider Specific Probe Medical Record Review Prepay Service Specific Probe Medical Record Review Postpay Provider Specific Probe Medical Record Review Postpay Service Specific Probe Medical Record Review Postpay Provider Specific Medical Record Review Postpay Service Specific Medical Record Review Monthly Reporting of Medical Review Savings
722	Clarifying Date and Timing Requirements for Certain Durable Medical Equipment Prosthetics Orthotics and Supplies (DMEPOS)
Medicare Contractor Beneficiary and Provider Communications (CMS-Pub. 100-09)	
	None
Medicare Quality Improvement Organization (CMS- Pub. 100-10)	
30	QIO Manual Chapter 16 – "Healthcare Quality Improvement Program" Quality Improvement Interventions Developing and Spreading Successful Interventions Documenting and Disseminating Results
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)	
	None
Medicare Business Partners Systems Security (CMS-Pub. 100-17)	
	None
Demonstrations (CMS-Pub. 100-19)	
172	Suppression of G9678 (Oncology Care Model Monthly Enhanced Oncology Services) Claims OCM Beneficiary Medicare Summary Notice
173	Medicare Care Choices Model - Per Beneficiary per Month Payment (PBPM) Implementation (eligibility updates and clarification)
174	Payment of G9678 (Oncology Care Model Monthly Enhanced Oncology Services) Claims for Beneficiaries Receiving Care in an Inpatient Setting
One Time Notification (CMS-Pub. 100-20)	
1815	Common Working File (CWF) to Archive Inactive Part B Consistency Edits
1816	Issued to a specific audience, not posted to Internet/ Intranet due to Sensitivity of Instruction
1817	Enrollment Data Base (EDB) and Common Working File (CWF) Data

	Resync- Analysis and Design
1818	Annual Updates to the Prior Authorization/Pre-Claim Review Federal Holiday Schedule Tables for Generating Reports
1819	Update to Common Working File (CWF) Blood Editing on Medicare Advantage (MA) Enrollees' Inpatient Claims for Indirect Medical Education (IME) Payment
1820	Issued to a specific audience, not posted to Internet/ Intranet due to Sensitivity of Instruction
1821	Issued to a specific audience, not posted to Internet/ Intranet due to Sensitivity Instruction
1822	Issued to a specific audience, not posted to Internet/ Intranet due to Sensitivity Instruction
1823	Issued to a specific audience, not posted to Internet/ Intranet due to Sensitivity Instruction
1824	Issued to a specific audience, not posted to Internet/ Intranet due to Sensitivity Instruction
1825	Issued to a specific audience, not posted to Internet/ Intranet due to Sensitivity Instruction
1826	Issued to a specific audience, not posted to Internet/ Intranet due to Sensitivity Instruction
1827	Issued to a specific audience, not posted to Internet/ Intranet due to Sensitivity Instruction
1828	Issued to a specific audience, not posted to Internet/ Intranet due to Sensitivity Instruction
1829	Issued to a specific audience, not posted to Internet/ Intranet due to Sensitivity Instruction
1830	Issued to a specific audience, not posted to Internet/ Intranet due to Sensitivity Instruction
1831	Introductory Letters for Suppliers and Providers Related to the Prior Authorization for Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Items
1832	Update FISS Editing to Include the Admitting Diagnosis Code Field
1833	Implementing the remittance advice messaging for the 20-hour weekly minimum for Partial Hospitalization Program services
1834	Analysis and Design Working Sessions for the Development of a Pre-Payment Common Additional Documentation Request (ADR) Letter
1835	Reason Codes 36233 and 36330 Bypass for Claims Submitted on the 72x Type of Bill for Services Provided to Beneficiaries with Acute Kidney Injury (AKI) and edits related to not separately payable drugs
1836	Analysis Only-Provider Number Validation Update for the Shared Systems Maintainer (SSM)
Medicare Quality Reporting Incentive Programs (CMS- Pub. 100-22)	
	None
Information Security Acceptable Risk Safeguards (CMS-Pub. 100-25)	
	None

Addendum II: Regulation Documents Published in the Federal Register (April through June 2017)

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-2Q17QPU.pdf

For questions or additional information, contact Terri Plumb (410-786-4481).

Addendum III: CMS Rulings (April through June 2017)

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 2017)

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
Screening for Hepatitis B Virus (HBV) Infection	210.6	197	04/28/2017	09/28/2016
Percutaneous Image-guided Lumbar Decompression for Lumbar Spinal Stenosis	150.13	196	05/22/21017	12/08/2016

Addendum V: FDA-Approved Category B Investigational Device Exemptions (IDEs) (April through June 2017)

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
G170059	BREATHID MCS	04/05/2017
G160267	Revolution Peripheral Atherectomy System	04/05/2017
G170058	Panoramic in ECGi in Patients with Recurrent AF after PV Isolation	04/06/2017
G170060	Fectoscopic Repair of Myelomeningocele (MMC) in Fetuses with Isolated Spina Bifida	04/07/2017
G170027	AquaBeam System Water II Study	04/10/2017
G170064	INDIGO Aspiration System	04/13/2017
G170065	Panoramic ECGi to guide Ablation of Non-Paroxysmal AF: Effect of Ibutilide on AF Source Location and Organization	04/13/2017
G170066	JET-PCB Trial	04/13/2017
G170067	Intramural Needle Ablation for the Treatment of Refractory Ventricular Arrhythmias	04/13/2017
G170068	CardioMEMS HF System	04/14/2017
G170071	Embosphere Microspheres	04/20/2017
G160156	LimFlow System	04/20/2017
G170073	Osia System	04/21/2017
G160257	Princess FILLER Lidocaine	04/26/2017
G170078	Avinger's Pantheris Atherectomy Catheter	04/27/2017
G170079	NovoTTF-200A (TTFields)	04/30/2017
G160224	Countour PVA, Embosphere and Embozene Particles	05/02/2017
BB17426	CliniMACS TCRalpha-beta/CD19 Combined Depletion System	05/02/2017
G160227	Svelte Sirolimus-Eluting Coronary Stent	05/03/2017
G170085	Guardant360 CDx Test	05/03/2017
G170087	Osia System	05/05/2017
G150110	Emervel Lips	05/05/2017
G170090	Artimes pro Balloon Dilatation Catheter	05/08/2017
G170049	RADAR: Real-time electrogram Analysis for Drivers of AtRial fibrillation	05/09/2017
G170095	RADIESSE (+) Lidocaine 1.5cc	05/11/2017
G170093	A Phase 2 Study of Reduced Therapy for Newly Diagnosed Average-Risk WNT-Driven Medulloblastoma Patients	05/12/2017
G170084	gammaCore-R	05/16/2017
BB17455	Cytori Celution System	05/17/2017
G170098	JUVEDERM VOLBELLA XC for Correction of Infraorbital Hollowing	05/18/2017
G160235	BuMA Supreme Biodegradable Drug Coated Coronary Stent System	05/18/2017
G170102	Foundation Medicine Blood First Assay Screening Trial (BFAST) Clinical Trial Assay (CTA)	05/19/2017
G170105	Insulin Pump System with Predictive Low Glucose Suspend	05/26/2017
G170109	SPY Portable Handheld Imaging (SPY-PHI) System (HH9000); IC2000 (Indocyanine Green for Injection, USP)	05/26/2017

IDE	Device	Start Date
G170112	SPY Portable Handheld Imaging (SPY-PHI) System (HH9000); IC2000 (Indocyanine Green for Injection, USP)	05/30/2017
G170114	Micra Atrial TRacking Using A Ventricular AccELerometer (MARVEL) clinical feasibility study	06/01/2017
G170111	MED-EL SYNCRONY Cochlear Implant System	06/02/2017
G170116	RETINA IMPLANT Alpha AMS	06/02/2017
G170118	TVRS Clip Delivery System, TVRS Steerable Guide Catheter	06/02/2017
G170110	Left Atrial Anatomy Reconstruction Using Model Based Fast Anatomical Mapping	06/05/2017
G170120	B-FAST bTMB CTA	06/06/2017
G170119	MAGE-A4 Immunohistochemistry (IHC) Clinical Trial Assay (CTA)	06/07/2017
G170125	myChoice HRD CDx	06/12/2017
G170128	Transdermal Compress	06/14/2017
G170081	XIENCE Apine Everolimus Eluting Coronary Stent System; XIENCE Xpedition Everolimus Eluting Coronary Stent System	06/15/2017
G170127	MagPro MST manufactured by MagVenture, Inc.	06/16/2017
G170129	Apollo System	06/16/2017
G170130	SurgiMed Collagen Matrix	06/16/2017
G170132	Belotero Balance with Integral Lidocaine (Project description)	06/16/2017
G170140	NY-ESO-1 Immunohistochemistry (IHC) Clinical Trial Assay (CTA)	06/21/2017
G170077	Exablate Model 4000 Type-1 system	06/22/2017
G170138	Telsa Magnetic Resonance Research Device	06/23/2017
G170144	Cardiva Mid-Bore Venous Vascular Closure System (VVCS)	06/23/2017
G170016	RxLAL, Light Delivery Device and Rx Sight Insertion Device	06/23/2017
G170139	Cochlear Implantation during Vestibular Schwannoma Removal or during Labyrinthectomy surgery for treatment of Meniere's disease	06/28/2017
G170147	RCStim Model 1114R or 1114L Soft Tissue Stimulator	06/28/2017
BB17524	Treatment of erectile dysfunction (ED)	06/29/2017
G170133	Med-El cochlear implant insertion electrode	06/30/2017
G170146	RestoreSensor SureScan MRI Implantable Neurostimulation System	06/30/2017

Addendum VI: Approval Numbers for Collections of Information (April through June 2017)

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 William Parham (410-786-4669).

Addendum VII: Medicare-Approved Carotid Stent Facilities, (April through June 2017)

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.			
Parkview Medical Center 400 W. 16th Street Pueblo, CO 81003	060020	04/05/2017	CO
St Francis Xavier Hospital 2095 Henry Tecklenburg Drive Charleston, SC 29414	420065	04/27/2017	SC
Garfield Medical Center 525 N. Garfield Avenue Monterey Park, CA 91754	050737	05/12/2017	CA
Kaiser Foundation Hospital Sacramento 2025 Morse Avenue Sacramento, CA 95825	1952476665	06/30/2017	CA
The following facilities have editorial changes (in bold).			
FROM: Oakwood Hospital and Medical Center **TO: Beaumont Hospital – Dearborn** 18101 Oakwood Boulevard Dearborn, MI 48123-2500 P.O Box 2500	230020	07/07/2005	MI
FROM: Howard Regional Health System **TO: Community Howard Regional Health** 3500 South Lafountain Street Kokomo, IN 46904-9011 P.O. Box 9011	150007	09/08/2005	IN
FROM: Brackenridge Hospital	450124	06/07/2005	TX

Facility	Provider Number	Effective Date	State
TO: Dell Seton Medical Center at The University of Texas 1500 Red River Street Austin, TX 78701			
The following facilities are terminations for this quarter.			
San Ramon Regional Medical Center 6001 Norris Canyon Road San Ramon, CA 94583	050689	06/07/2005	CA

Addendum VIII: American College of Cardiology's National Cardiovascular Data Registry Sites (April through June 2017)

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.		
Interfaith Medical Center	Brooklyn	NY
Mid-Columbia Medical Center	The Dalles	OR
Midstate Medical Center	Meriden	CT
Olmsted Medical Center	Rochester	MN
UNMH - Sandoval Regional Medical Center	Rio Rancho	NM
Houston Methodist The Woodlands	The Woodlands	TX
Glacial Ridge Hospital District	Glenwood	MN
Promedica Defiance Regional Hospital	Defiance	OH
Alaska Cardiovascular Surgery Center, LLC	Anchorage	AK
Lakeview Hospital	Bountiful	UT
Fort Sutter Surgery Center, L.P.	Sacramento	CA
Holy Cross Germantown Hospital	Germantown	MD
Ellwood City Hospital	Ellwood City	PA
Marshfield Clinic - Wausau Center	Marshfield	WI

Addendum IX: Active CMS Coverage-Related Guidance Documents (April through June 2017)

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 2017)

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 2017)

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 2017)

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.

There were no additions, deletions, or editorial changes 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).

Addendum XIII: Lung Volume Reduction Surgery (LVRS) (April through June 2017)

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 2017)

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 2017)

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. 2017–16252 Filed 8–3–17; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Comment Request

Title: Form OCSE–396, ''Child Support Enforcement Program Quarterly Financial Report'', Form OCSE–34, ''Child Support Enforcement Program Quarterly Collection Report''.

OMB No.: 0970–0181.

Description: Form OCSE–396 and Form OCSE–34 are financial reports submitted following the end of each fiscal quarter by grantees administering the Child Support Enforcement Program in accordance with plans approved under title IV–D of the Social Security Act. Submission of these forms enables grantees to meet their statutory and regulatory requirement to report program expenditures and child support collections, respectively, from the previous fiscal quarter.

States use Form OCSE–396 to report quarterly expenditures made in the previous quarter and to estimate program expenditures to be made and the incentive payments to be earned in the upcoming quarter. The Administration for Children and Families provides Federal funding to States for the Child Support Enforcement Program at the rate of 66 percent for all allowable and legitimate administrative costs of this program.

Tribes use OMB Form SF–425 to report quarterly expenditures made in the previous quarter. Form SF–425 is not included as part of this comment request.

As part of this request, minor changes are being proposed only in response to amendments to Federal regulations:

- 45 CFR 304.25(b) was amended to extend the quarterly reporting deadline for both reports from ''30'' to ''45'' days after the end of each fiscal quarter.
- 45 CFR part 95 was amended to require that all expenditures for a Statewide Child Support Enforcement System will now require an approved Advanced Planning Document (APD). Therefore, Line 6 on Form OCSE–396, ''ADP Costs Without APD Required'' is being eliminated as no longer necessary.

The necessary instructions are being amended in response to both changes.

Respondents: 54 States (including Puerto Rico, Guam, the Virgin Islands and the District of Columbia) for Forms OCSE–396 and OCSE–34 plus approximately 60 Tribes for Form OCSE–34.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Form OCSE–396	54	4	6	1,296
Form OCSE–34	114	4	14	6,384

Estimated Total Annual Burden Hours: 7,680.

Additional Information: Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 330 C Street SW., Washington, DC 20201. Attention Reports Clearance Officer. All requests should be identified by the title of the information collection. Email address: *infocollection@acf.hhs.gov.*

OMB Comment: 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. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, Email: *OIRA_SUBMISSION@OMB.EOP.GOV,* Attn: Desk Officer for the Administration for Children and Families.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 2017–16390 Filed 8–3–17; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Meeting of the Presidential Advisory Council on HIV/AIDS

AGENCY: Office of the Assistant Secretary for Health, Office of the Secretary, Department of Health and Human Services.

ACTION: Notice.

SUMMARY: As stipulated by the Federal Advisory Committee Act, the U.S. Department of Health and Human Service is hereby giving notice that the Presidential Advisory Council on HIV/AIDS (PACHA or the Council) will be holding a meeting and will discuss recommendations regarding programs, policies, and research to promote effective, prevention, treatment and cure of HIV disease and AIDS. The meeting will be open to the public.

DATES: The Council meeting is scheduled to convene on Wednesday, August 30, 2017 from 9:00 a.m. to approximately 5:00 p.m. (ET). The meeting will be open to the public.

ADDRESSES: 200 Independence Avenue SW., Washington, DC 20201 in the Penthouse (eighth floor), Room 800.

FOR FURTHER INFORMATION CONTACT: Ms. Caroline Talev, Public Health Analyst, Presidential Advisory Council on HIV/AIDS, 330 C Street SW., Room L106B, Washington, DC 20024; (202) 795–7622 or *Caroline.Talev@hhs.gov.* More detailed information about PACHA can be obtained by accessing the Council's page on the *AIDS.gov* site at *www.aids.gov/pacha.*

SUPPLEMENTARY INFORMATION: PACHA was established by Executive Order 12963, dated June 14, 1995, as amended by Executive Order 13009, dated June 14, 1996. In a memorandum, dated July 13, 2010, and under Executive Order 13703, dated July 30, 2015, the President gave certain authorities to the PACHA for implementation of the National HIV/AIDS Strategy for the United States (Strategy). PACHA is currently operating under the authority given in Executive Order 13708, dated September 30, 2015.

PACHA provides advice, information, and recommendations to the Secretary regarding programs, policies, and research to promote effective treatment, prevention, and cure of HIV disease and AIDS, including considering common co-morbidities of those infected with HIV as needed, to promote effective HIV prevention and treatment and quality services to persons living with HIV disease and AIDS.

Substantial progress has been made in addressing the domestic HIV epidemic since the Strategy was released in July 2010. Under Executive Order 13703, the National HIV/AIDS Strategy for the United States: Updated to 2020 (Updated Strategy) was released. PACHA shall contribute to the federal effort to improve HIV prevention and care.

The functions of the Council are solely advisory in nature.

The Council consists of not more than 25 members. Council members are selected from prominent community leaders with particular expertise in, or knowledge of, matters concerning HIV and AIDS, public health, global health, philanthropy, marketing or business, as well as other national leaders held in high esteem from other sectors of society. Council members are appointed by the Secretary or designee, in consultation with the White House. The agenda for the upcoming meeting will be posted on the *HIV.gov* Web site at *https://www.hiv.gov/federal-response/pacha/about-pacha.*

Public attendance at the meeting is limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify Caroline Talev at *Caroline.Talev@hhs.gov.* Due to space constraints, pre-registration for public attendance is advisable and can be accomplished by contacting Caroline Talev at *Caroline.Talev@hhs.gov* by close of business on Wednesday, August 23, 2017. Members of the public will have the opportunity to provide comments during the meeting. Comments will be limited to two minutes per speaker. Any individual who wishes to participate in the public comment session must register with Caroline Talev at *Caroline.Talev@hhs.gov* by close of business on Wednesday, August 23, 2017; registration for public comment will not be accepted by telephone. Individuals are encouraged to provide a written statement of any public comment(s) for accurate minute taking purposes. Any members of the public who wish to have printed material distributed to PACHA members at the meeting are asked to submit, at a minimum, 1 copy of the material(s) to Caroline Talev, no later than close of business on Wednesday, August 23, 2017.

Dated: July 20, 2017.

B. Kaye Hayes,

Executive Director, Presidential Advisory Council on HIV/AIDS.

[FR Doc. 2017–16465 Filed 8–3–17; 8:45 am]

BILLING CODE 4150–43–P

DEPARTMENT OF HOMELAND SECURITY

Agency Information Collection Activities: Proposed Collection; Comment Request; The Department of Homeland Security, Office of Emergency Communications, SAFECOM Nationwide Survey (SNS)

AGENCY: National Protection and Programs Directorate, DHS.

ACTION: 30-Day notice and request for comments; New Collection: 1670–NEW.

SUMMARY: The Department of Homeland Security (DHS), National Protection and Programs Directorate (NPPD), Office of Cybersecurity and Communications (CS&C), Office of Emergency Communications, will submit the following Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995. DHS previously published this ICR in the **Federal Register** for 60 days. The notice published as 60-Day Request for Comment on Thursday, April 27, 2017. DHS received comments from two stakeholders indicating an appreciation for public outreach. As a next step in the administrative process, a second notice will be published in the **Federal Register**. Its purpose is to allow an additional 30 days for the public to provide comments about the notice.

DATES: Comments are encouraged and will be accepted until September 5, 2017. DHS and OMB conducts this process in accordance with *Controlling Paperwork Burdens on the Public* rules and regulations. 5 CFR 1320.1 (1995).

ADDRESSES: Interested persons are invited to submit written comments on the proposed ICR to the Office of Information and Regulatory Affairs, Office of Management and Budget (OMB). Comments should be addressed to OMB Desk Officer, Department of Homeland Security and sent via electronic mail to *oira_submission@omb.eop.gov* or faxed to (202) 395–5806.

SUPPLEMENTARY INFORMATION: Enactment of 6 U.S.C. 571 governs the Office of Emergency Communications (OEC) and establishes a Director with specific responsibilities. This includes assisting the DHS Secretary in developing and implementing a program to support and promote the ability of emergency response providers and relevant government officials to continue to communicate in the event of natural disasters, acts of terrorism, and other man-made disasters; and ensure, accelerate, and attain interoperable emergency communications nationwide. In addition, 6 U.S.C. 573 authorizes the DHS Secretary acting through the OEC Director to conduct a baseline assessment of communications capabilities among emergency response providers and relevant government officials at all levels of government no less than once every five years. OEC is tasked with conducting a periodic nationwide assessment of emergency communications.

OEC's governing statute provides a framework for its periodic assessment. Accordingly, OEC, in coordination with its stakeholder partners, developed the *SAFECOM Nationwide Survey (SNS).* The survey's purpose is to gather information to assess capabilities currently available, and identify gaps based on the needs of emergency response providers. This information will allow OEC and its stakeholders to understand critical capabilities more clearly, and to target resources more efficiently for communications during response situations of all scales and scope, from day-to-day to out-of-the-ordinary situations.

To gather baseline assessment information, OEC will deploy four versions of the *SAFECOM Nationwide Survey* (SNS) tailored to address emergency response entities at each level of government: Federal, State and territorial, tribal, and local. Each SNS version is built upon a foundation of core planning elements identified by OEC and its stakeholders as fundamental to achieve open and secure communications operability, interoperability, and continuity. These elements are interdependent critical success factors that must be addressed to plan for and implement public safety communications capabilities. These elements are recognized as *Governance, Standard Operating Procedures, Training and Exercises, Technology, Usage, Security and Equipment.*

The SNS questions align with each of these elements. This design enables DHS to determine jurisdictional capability levels of operability, interoperability, and continuity as they collectively pertain to the use of emergency communications. For example, Governance questions will pertain to matters related to decision-making groups, agreements, funding, and strategic planning. Standard Operating Procedure questions will focus on procedures, guidelines, and content. Training and Exercise questions will focus on their nature, scope, and frequency. Technology questions will focus on infrastructure, solutions, and information-sharing. Usage questions will address frequency of use, proficiency, and resource

capacity. Security will focus on cybersecurity in the context of emergency communications. Finally, Equipment questions focuses on the types of equipment or systems used. These SNS elements and sub-elements set forth the DHS OEC assessment framework. Collectively, will enable DHS OEC to fulfill its governing authority and identify a baseline of nationwide emergency communications capabilities.

This is a new information collection. OMB is particularly interested in comments that:

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

2. Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

3. Enhance the quality, utility, and clarity of the information to be collected; and minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submissions of responses.

Analysis

Agency: Department of Homeland Security, National Protection and Programs Directorate, Office of Cybersecurity and Communications, Office of Emergency Communications.

OMB Number: 1670–NEW.

Frequency: Once every five years.

Affected Public: Federal, State, local and private sector emergency response personnel.

Number of Respondents: 3,002 annually.

Estimated Time Per Respondent: 30 minutes.

Total Burden Hours: 1,501 annual burden hours.

Dated: July 28, 2017.

David Epperson,

Chief Information Officer.

[FR Doc. 2017–16388 Filed 8–3–17; 8:45 am]

BILLING CODE 9110–9P–P

DEPARTMENT OF THE INTERIOR

Bureau of Ocean Energy Management

[Docket No. BOEM–2017–0034]

Final Programmatic Environmental Impact Statement for Geological and Geophysical Activities on the Gulf of Mexico Outer Continental Shelf MMAA104000

AGENCY: Bureau of Ocean Energy Management, Interior.

ACTION: Notice of availability of a Final Programmatic Environmental Impact Statement.

SUMMARY: The Bureau of Ocean Energy Management (BOEM) is announcing the availability of a Final Programmatic Environmental Impact Statement (EIS) for evaluating potential environmental effects of geological and geophysical (G&G) activities in OCS waters of the GOM. The Final Programmatic EIS analyzes potential impacts of the proposed action, provides an analysis of reasonable alternatives to the proposed action, and identifies BOEM's preferred alternative. The Final Programmatic EIS considers G&G activities for BOEM's three programs, *i.e.,* Oil and Gas, Renewable Energy, and Marine Minerals. These activities include, but are not limited to, seismic surveys (deep-penetration and high-resolution geophysical), sidescan-sonar surveys, electromagnetic surveys, and geological and geochemical sampling. The Final Programmatic EIS also evaluates mitigation measures to reduce potential impacts of G&G activities on marine resources, such as sound impacts to marine species and bottom-disturbance impacts on benthic communities and cultural resources.

The Final Programmatic EIS is available on BOEM's Web sites at *http://www.boem.gov/GOM-G-G-PEIS* and *http://www.boem.gov/nepaprocess/.* BOEM will primarily distribute digital copies of the Final Programmatic EIS on compact discs. You may request a paper copy or the location of a library with a paper copy of the Final Programmatic EIS from Mr. Greg Kozlowski by telephone at (504) 736–2512 or by email at *greg.kozlowski@boem.gov.*

FOR FURTHER INFORMATION CONTACT: Jill Lewandowski, Ph.D., Chief, Division of Environmental Assessment, Office of Environmental Programs, Bureau of Ocean Energy Management, 45600 Woodland Road, VAM–OEP, Sterling, VA 20166 or by email at *gomggeis@boem.gov.*

Authority: This Notice of Availability is published pursuant to the regulations (40 CFR part 1503 and 43 CFR part 46) implementing the provisions of the National Environmental Policy Act of 1969, as amended (42 U.S.C. 4321 *et seq.* (1988)).

Dated: July 31, 2017.

Walter D. Cruickshank,

Acting Director, Bureau of Ocean Energy Management.

[FR Doc. 2017–16421 Filed 8–3–17; 8:45 am]

BILLING CODE 4310–MR–P

DEPARTMENT OF THE INTERIOR

Bureau of Ocean Energy Management

[Docket No. BOEM–2017–0041]

Final Supplemental Environmental Impact Statement for the Cape Wind Energy Project MMAA104000

AGENCY: Bureau of Ocean Energy Management, Interior.

ACTION: Notice of availability of a final supplemental environmental impact statement.

SUMMARY: The Bureau of Ocean Energy Management (BOEM) is announcing the availability of a Final Supplemental Environmental Impact Statement (Final SEIS) for the Cape Wind Energy Project. This supplement to the 2009 Final EIS has been prepared in response to a 2016 remand order of the U.S. Court of Appeals for the District of Columbia Circuit in *Public Employees for Environmental Responsibility* v. *Hopper* (see **SUPPLEMENTARY INFORMATION** for details).

FOR FURTHER INFORMATION CONTACT: Michelle Morin, BOEM Office of Renewable Energy Programs, 45600 Woodland Road, Sterling, Virginia 20166, (703) 787–1722 or *michelle.morin@boem.gov.*

SUPPLEMENTARY INFORMATION: On July 5, 2016, the U.S. Court of Appeals for the District of Columbia Circuit vacated the 2009 Cape Wind Energy Project Final EIS and ordered that BOEM: ''supplement [the EIS] with adequate geological surveys before Cape Wind may begin construction.'' *Public Employees for Environmental Responsibility* v. *Hopper,* 827 F.3d 1077, 1084 (D.C. Cir. 2016). The Court opined that: ''[w]ithout adequate geological surveys, the [BOEM] cannot 'ensure that the seafloor [will be] able to support' wind turbines.'' *Id.* at 1083. While the Court found that: ''[BOEM] therefore had violated NEPA (National Environmental Policy Act)'' the Court noted that ''. . . [it] does not necessarily mean that the project must be halted or that Cape Wind must redo the regulatory approval process.'' *Id.* at

1083–4. The Court explicitly left undisturbed BOEM's 2010 decision to issue a lease to Cape Wind Associates (CWA) and BOEM's 2011 decision to approve CWA's Construction and Operations Plan (COP) for the Cape Wind Energy Project. *Id.* at 1084. In response to the Circuit Court's remand order, BOEM published the Draft SEIS for the Cape Wind Energy Project on March 31, 2017.

The Draft SEIS considered the only two alternatives that remained relevant as a result of the Court's remand order and CWA's lease and the approved Cape Wind COP: The Proposed Action (affirming BOEM's issuance of the existing lease), and the No Action Alternative (requiring BOEM to rescind lease issuance). BOEM published a notice in the **Federal Register** on March 31, 2017, to announce the availability of the Draft SEIS and initiate a 45-day public comment period (82 FR 16060). All the comments received on the Draft SEIS are available for public viewing and can be found at: *http://www.regulations.gov* by searching for docket ID BOEM–2017–0008.

In the Final SEIS for the Cape Wind Energy Project, BOEM examines the available geological survey data, including the geotechnical data and reports submitted to BOEM since the 2009 Final EIS, and any other relevant data that relate to the adequacy of the seafloor to support wind turbines in the lease area. The Final SEIS also includes a summary of all the comments received on the Draft SEIS and BOEM's responses to those comments. The Final SEIS can be found on BOEM's Web site at: *https://www.boem.gov/Massachusetts-Cape-Wind/.*

Authority: This notice of availability to prepare a Final SEIS is in compliance with NEPA, as amended (42 U.S.C. 4231 *et seq.*), and is published pursuant to 40 CFR 1506.6.

Dated: July 31, 2017.

Walter D. Cruickshank,

Acting Director, Bureau of Ocean Energy Management.

[FR Doc. 2017–16422 Filed 8–3–17; 8:45 am]

BILLING CODE 4310–MR–P

INTERNATIONAL TRADE COMMISSION

Notice of Receipt of Complaint; Solicitation of Comments Relating to the Public Interest

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission has received a complaint entitled *Certain Microfluidic Devices DN 3239;* the Commission is soliciting comments on any public interest issues raised by the complaint or complainant's filing pursuant to the Commission's Rules of Practice and Procedure.

FOR FURTHER INFORMATION CONTACT: Lisa R. Barton, Secretary to the Commission, U.S. International Trade Commission, 500 E Street SW., Washington, DC 20436, telephone (202) 205–2000. The public version of the complaint can be accessed on the Commission's Electronic Document Information System (EDIS) at *https://edis.usitc.gov,* and will be available for inspection during official business hours (8:45 a.m. to 5:15 p.m.) in the Office of the Secretary, U.S. International Trade Commission, 500 E Street SW., Washington, DC 20436, telephone (202) 205–2000.

General information concerning the Commission may also be obtained by accessing its Internet server at United States International Trade Commission (USITC) at *https://www.usitc.gov*. The public record for this investigation may be viewed on the Commission's Electronic Document Information System (EDIS) at *https://edis.usitc.gov*. Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on (202) 205–1810.

SUPPLEMENTARY INFORMATION: The Commission has received a complaint and a submission pursuant to § 210.8(b) of the Commission's Rules of Practice and Procedure filed on behalf of Bio-Rad Laboratories, Inc. and Lawrence Livermore National Security, LLC on July 31, 2017. The complaint alleges violations of section 337 of the Tariff Act of 1930 (19 U.S.C. 1337) in the importation into the United States, the sale for importation, and the sale within the United States after importation of certain microfluidic devices. The complaint names as a respondent 10X Genomics, Inc. of Pleasanton, CA. The complainant requests that the Commission issue a limited exclusion order, a cease and desist order, and impose a bond upon respondents' alleged infringing articles during the 60-day Presidential review period pursuant to 19 U.S.C. 1337(j).

Proposed respondents, other interested parties, and members of the public are invited to file comments, not to exceed five (5) pages in length, inclusive of attachments, on any public interest issues raised by the complaint or § 210.8(b) filing. Comments should address whether issuance of the relief specifically requested by the complainant in this investigation would affect the public health and welfare in the United States, competitive conditions in the United States economy, the production of like or directly competitive articles in the United States, or United States consumers.

In particular, the Commission is interested in comments that:

(i) Explain how the articles potentially subject to the requested remedial orders are used in the United States;

(ii) identify any public health, safety, or welfare concerns in the United States relating to the requested remedial orders;

(iii) identify like or directly competitive articles that complainant, its licensees, or third parties make in the United States which could replace the subject articles if they were to be excluded;

(iv) indicate whether complainant, complainant's licensees, and/or third party suppliers have the capacity to replace the volume of articles potentially subject to the requested exclusion order and/or a cease and desist order within a commercially reasonable time; and

(v) explain how the requested remedial orders would impact United States consumers.

Written submissions must be filed no later than by close of business, eight calendar days after the date of publication of this notice in the **Federal Register**. There will be further opportunities for comment on the public interest after the issuance of any final initial determination in this investigation.

Persons filing written submissions must file the original document electronically on or before the deadlines stated above and submit 8 true paper copies to the Office of the Secretary by noon the next day pursuant to § 210.4(f) of the Commission's Rules of Practice and Procedure (19 CFR 210.4(f)). Submissions should refer to the docket number (''Docket No. 3239'') in a prominent place on the cover page and/or the first page. (*See* Handbook for Electronic Filing Procedures, Electronic Filing Procedures).[1] Persons with questions regarding filing should contact the Secretary (202–205–2000).

Any person desiring to submit a document to the Commission in confidence must request confidential

[1] Handbook for Electronic Filing Procedures: *https://www.usitc.gov/documents/handbook_on_filing_procedures.pdf.*

treatment. All such requests should be directed to the Secretary to the Commission and must include a full statement of the reasons why the Commission should grant such treatment. *See* 19 CFR 201.6. Documents for which confidential treatment by the Commission is properly sought will be treated accordingly. All such requests should be directed to the Secretary to the Commission and must include a full statement of the reasons why the Commission should grant such treatment. *See* 19 CFR 201.6. Documents for which confidential treatment by the Commission is properly sought will be treated accordingly. All information, including confidential business information and documents for which confidential treatment is properly sought, submitted to the Commission for purposes of this Investigation may be disclosed to and used: (i) By the Commission, its employees and Offices, and contract personnel (a) for developing or maintaining the records of this or a related proceeding, or (b) in internal investigations, audits, reviews, and evaluations relating to the programs, personnel, and operations of the Commission including under 5 U.S.C. Appendix 3; or (ii) by U.S. government employees and contract personnel,[2] solely for cybersecurity purposes. All nonconfidential written submissions will be available for public inspection at the Office of the Secretary and on EDIS.[3]

This action is taken under the authority of section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), and of §§ 201.10 and 210.8(c) of the Commission's Rules of Practice and Procedure (19 CFR 201.10, 210.8(c)).

By order of the Commission.

Issued: July 31, 2017.

Lisa R. Barton,

Secretary to the Commission.

[FR Doc. 2017–16394 Filed 8–3–17; 8:45 am]

BILLING CODE 7020–02–P

[2] All contract personnel will sign appropriate nondisclosure agreements.

[3] Electronic Document Information System (EDIS): *https://edis.usitc.gov.*

DEPARTMENT OF JUSTICE

Bureau of Alcohol, Tobacco, Firearms and Explosives

[OMB Number 1140–0007]

Agency Information Collection Activities; Proposed eCollection eComments Requested; Revision of a Currently Approved Collection; Release and Receipt of Imported Firearms, Ammunition and Defense Articles; ATF F 6A (5330.3C)

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

ACTION: 60-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 collection 1140–0007 is being revised to change all references from ''Implements of War'' to ''Defense Articles'' including the title of the collection, which will be changed to Release and Receipt of Imported Firearms, Ammunition, and Defense Articles.

DATES: Comments are encouraged and will be accepted for 60 days until October 3, 2017.

FOR FURTHER INFORMATION CONTACT: If you have additional comments, particularly with respect to the estimated public burden or associated response time, have suggestions, need a copy of the proposed information collection instrument with instructions, or desire any additional information, please contact Desiree M. Dickinson, ATF Firearms and Explosives Imports Branch either by mail at 244 Needy Road, Martinsburg, WV 25405, or by email at *desiree.dickinson@atf.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 (*check justification or form 83): Revision of a currently approved collection.

2. *The Title of the Form/Collection:* Release and Receipt of Imported Firearms, Ammunition, and Defense Articles.

3. *The agency form number, if any, and the applicable component of the Department sponsoring the collection:*

Form number (if applicable): ATF F 6A (5330.3C).

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: Individuals or households.

Other (if applicable): Business or other for-profit, and not-for-profit institutions.

Abstract: The data provided by this information collection request is used by ATF to determine if articles imported meet the statutory and regulatory criteria for importation and if the articles shown on the permit application have been actually imported.

5. *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* An estimated 28,000 respondents will utilize the form, and it will take each respondent approximately 35 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 16,333 hours which is equal to 28,000 (# of respondents) * .58332 (35 minutes).

7. *An Explanation of the Change in Estimates:* The adjustments associated with this collection are an increase in respondents by 8,000 and an increase in the total burden hours by 4,666.

If additional information is required contact: Melody Braswell, Department

Clearance Officer, United States Department of Justice, Justice Management Division, Policy and Planning Staff, Two Constitution Square, 145 N Street NE., 3E.405A, Washington, DC 20530.

Dated: August 1, 2017.

Melody Braswell,

Department Clearance Officer for PRA, U.S. Department of Justice.

[FR Doc. 2017–16431 Filed 8–3–17; 8:45 am]

BILLING CODE 4410–FY–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 17–22]

John D. Bray-Morris, M.D.; Decision and Order

On February 15, 2017, the Assistant Administrator, Division of Diversion Control, Drug Enforcement Administration, issued an Order to Show Cause to John D. Bray-Morris, M.D. (hereinafter, Respondent), of Moriarty, New Mexico. The Show Cause Order proposed the revocation of Respondent's DEA Certificate of Registration No.FB5001538, on the ground that he does not hold authority to dispense controlled substances in New Mexico, the State in which he is registered with the Agency. Show Cause Order, at 1 (citing 21 U.S.C. 824(a)(3)).

With respect to the Agency's jurisdiction, the Show Cause Order alleged that Respondent is registered as a practitioner authorized to dispense controlled substances in schedules II through V, at the registered address of 1108 Route 66, P.O. Box 1520, Moriarty, New Mexico. *Id.* The Show Cause Order alleged that this registration expires on July 31, 2017. *Id.*

As for the substantive basis of the proposed action, the Show Cause Order alleged that on January 13, 2017, ''the New Mexico [Medical] Board . . . entered an Order of Immediate Suspension and Notice of Contemplated Action . . . suspending [Respondent's] New Mexico Medical License No. 2003–0404 effective on that same date, which remains in effect until further Order of the Board, and that the Board contemplates additional action of restricting, suspending or revoking [his] license to practice as a physician.'' *Id.* at 2. The Show Cause Order thus alleged that the Board's ''Order prohibits [Respondent] from practicing medicine in the State of New Mexico.'' *Id.*

The Show Cause Order also alleged that the Board's Order of Immediate Suspension was based on Respondent's violation of an earlier Board order which suspended his medical license for violations of the State's Medical Practice Act. *Id.* The Show Cause Order alleged that these included ''unprofessional or dishonorable conduct, including . . . injudicious prescribing . . . and violation of a drug law.'' *Id.* The Show Cause Order alleged that the earlier Board order ''commanded that [Respondent] abstain completely from the use of mind-altering substances and controlled substances . . . [and] that [he] enroll in and maintain compliance with, [the] New Mexico Monitored Treatment Program for habitual or excessive use of intoxicants or drugs.'' *Id.* at 2.

The Show Cause Order further alleged that the Board's 2017 Order of Immediate Suspension was based on numerous new allegations, including, *inter alia,* that Respondent ''resumed the personal and unlawful use of opioid drugs'' and that he ''willfully thwarted the Board's drug screenings.'' *Id.* The allegations also include that he ''prescribed large and varied amounts of controlled substances to patients without adequate medical justification,'' engaged in ''injudicious and non-therapeutic prescribing of controlled substances,'' ''failed to screen patients for substance abuse disorders,'' ''diverted controlled substances that [he] prescribed . . . to patients from those patients for [his] personal use,'' and ''falsified'' medical records ''to justify the prescribing of controlled substances.'' *Id.*

The Show Cause Order thus alleged that pursuant to the Board's Order, Respondent is ''not permitted to practice medicine in New Mexico'' and therefore ''lack[s] authority to handle controlled substances in'' the State. *Id.* at 3. The Show Cause Order also asserted that Respondent's ''lack of authority to handle controlled substances in New Mexico constitutes grounds to revoke [his] DEA [r]egistration.'' *Id.* at 3 (citing 21 U.S.C. 802(21) and 824(a)(3)).

The Show Cause Order notified Respondent of his right to request a hearing on the allegations or to submit a written statement while waiving his right to a hearing, and the procedure for electing either option. Show Cause Order, at 3–4 (citing 21 CFR 1301.43). Finally, the Order notified Respondent of his right to submit a corrective action plan. *See* 21 U.S.C. 824(c)(2)(C).

On February 22, 2017, a DEA Diversion Investigator assigned to the Albuquerque District Office personally served the Show Cause Order on Respondent. Gov. Mot. for Summ. Disp., at GX D, at 1–2. Thereafter, on March 23, 2017, Respondent, through his counsel, requested a hearing on the allegations and a stay pending resolution of the New Mexico Medical Board matter, then scheduled for May 17–19, 2017. *See* Resp. Hrng. Req. The matter was placed on the docket of the Office of Administrative Law Judges, and assigned to Chief Administrative Law Judge John J. Mulrooney, II (hereinafter, CALJ).

On March 23, 2017, the CALJ ordered the Government to ''file proof of service'' as well as evidence to support the lack of state authority allegation, as well as any motion for summary disposition, any motion challenging the timeliness of the hearing request, and any response to Respondent's stay request by March 31, 2017 at 2 p.m. *See* Order Directing the Filing of Government Evidence of Lack of State Authority Allegation and Briefing Schedule. The CALJ's order also directed that, in the event the Government filed a motion for summary disposition or a motion challenging the timeliness of his hearing request, Respondent was to file any response by April 10, 2017 at 2 p.m. *Id.*

On March 31, 2017, the Government filed its Motion for Summary Disposition. *See* Gov. Mot. for Summ. Disp. As support for its Motion, the Government provided a copy of Respondent's Certificate of Registration showing that he is registered in New Mexico, a certified copy of the New Mexico Medical Board's Order of Immediate Suspension and Notice of Contemplated Action (Jan. 13, 2017), a printout of Respondent's licensing status as of March 25, 2017 from the Board's Web site, and a Declaration from a Diversion Investigator (DI). *Id.* at Exhibits A–D. Based on the suspension of his medical license by the New Mexico Medical Board, the Government moved for summary disposition and a recommendation by the ALJ that Respondent's DEA practitioner's registration be revoked and that any pending applications for a registration in New Mexico be denied. Mot. for Summ. Disp., at 8. The Government also requested that the CALJ deny Respondent's requests for a hearing and a stay of the proceeding. *Id.*

On April 10, 2017, Respondent filed his reply, requesting that the ALJ deny the Government's motion and stay the matter until after the Board hearing. Respondent's Reply, at 1. While Respondent admitted that his license to practice medicine in New Mexico had been suspended, he stated that ''he has not yet had an opportunity to challenge the allegations in the . . . Order'' and that ''a due process hearing [was]

scheduled for May 17–18, 2017.'' *Id.* Respondent stated that he ''contests many of the allegations contained in the Summary Suspension Order and the Notice of Contemplated Action'' and that ''it will not be appropriate or proportional discipline for the Medical Board to uphold the suspension or to revoke his license.'' *Id.* at 1–2.

Respondent also argued that ''[t]he plain language of Section 824(a)(3) provides that the loss of state authority constitutes a discretionary, not mandatory, basis for revocation.'' *Id.* at 2. He further argued that ''a stay . . . would afford [him] with his due process right to be heard in a meaningful manner in the State . . . proceeding.'' *Id.* at 2 (citation omitted). He also argued that the Government would not suffer any prejudice should a stay be granted because ''the Medical Board proceeding will be completed within the next few months.'' *Id.* And finally, he contended that ''[i]f . . . [he] prevailed in his administrative hearing in front of the Medical Board, it would be contrary to due process considerations and judicial economy to then force [him] to reapply for his'' DEA registration. *Id.*

On April 11, 2017, the CALJ granted the Government's motion and recommended that Respondent's registration be revoked. Order Denying The Respondent's Request For A Stay; Granting The Government's Motion For Summary Disposition; And Recommended Rulings, Findings Of Fact, Conclusions Of Law, And Decision of the Administrative Law Judge (hereinafter, R.D.), at 4–5.

Denying Respondent's request for a stay, the CALJ noted that the Agency has repeatedly held that ''revocation is warranted even where a practitioner's state authority has been summarily suspended and the State has yet to provide the practitioner with a hearing to challenge the State's action and at which he . . . may ultimately prevail.'' *Id.* at 3 (quoting *Kamal Tiwari,* 76 FR 71604, 71606 (2011)). The CALJ also explained that ''[e]ven when the Respondent is actively engaged in appealing a temporary decision, the Agency has noted that '[i]t is not DEA's policy to stay [administrative] proceedings . . . while registrants litigate in other forums,'' *id.* (quoting *Newcare Home Health Servs.,* 72 FR 42126, 42127 n.2), and that a stay ''is 'unlikely to ever be justified' due to ancillary proceedings.'' *Id.* at 3–4 (citing *Grider Drug #1 & Grider Drug #2,* 77 FR 44070, 44104 n.97 (2012)).[1]

The CALJ also granted the Government's motion for summary disposition. *Id.* at 6. According to the CALJ, ''[d]espite the discretionary language set forth in [section] 824(a)(3) and highlighted by the Respondent . . . DEA has long held that possession of authority under state law to dispense controlled substances is not only a prerequisite to obtaining a DEA registration but also an essential condition for maintaining it.'' *Id.* at 4 (citing cases). The CALJ then explained that ''[t]he basis for the Agency's position lies with two other statutes in the Controlled Substances Act (CSA) which requires that, in order to obtain or maintain a DEA registration, a practitioner must be authorized to handle controlled substances in the state in which he practices.'' *Id.* (citing 21 U.S.C. 823(f) and 802(21)). The CALJ then explained that ''[b]ecause, in the Agency's view, 'possessing authority under state law to handle controlled substances is an essential condition for holding a DEA registration,' the Agency has consistently held that 'the CSA requires the revocation of a registration issued to a practitioner who lacks [such] authority.' '' *Id.* at 5 (citations omitted). Because there is ''no dispute . . . that . . . Respondent currently lacks state authority to handle controlled substances in New Mexico due to the Board[']s Jan. 13, 2017] Order,'' the CALJ held that ''he is not entitled to maintain his . . . registration'' and granted the Government's motion for summary disposition. *Id.* at 6.

Neither party filed exceptions to the CALJ's Recommended Decision. Thereafter, the record was forwarded to my Office for Final Agency Action. Having considered the record and the Recommended Decision, I adopt the CALJ's recommendation that I revoke Respondent's registration.[2] I make the following factual findings.

Findings

Respondent holds DEA Certificate of Registration No. FB5001538, pursuant to which he is authorized to dispense controlled substances in schedules II–V as a practitioner, at the registered address of 1108 Route 66, P.O. Box 1520, Moriarty, New Mexico. Mot. for Summ. Disp., at GX A. His registration does not expire until July 31, 2017. *Id.*

On January 13, 2017, the New Mexico Medical Board issued an Order of Immediate Suspension and Notice of Contemplated Action to Respondent, suspending his license to practice medicine. Mot. for Summ. Disp., Exhibit B, at 1–8. According to Respondent, a Board hearing was scheduled for May 17–18, 2017. Resp. Reply, at 1. However, subsequent to the CALJ's issuance of his decision, Respondent has submitted no evidence showing that his license had been reinstated, and according to the Board's Web site of which I take official notice, Respondent's license to practice medicine in New Mexico remains suspended as of the date of this Order. *See* Respondent's Reply, at 1, *see also* Board Web site at *http://cgi.docboard.org/cgi-shl/nhayer.exe.*[3]

Discussion

Pursuant to 21 U.S.C. 824(a)(3), the Attorney General is authorized to suspend or revoke a registration issued under section 823 of the Controlled Substances Act (CSA), ''upon a finding that the registrant . . . has had his State license . . . suspended [or] revoked . . . by competent State authority and is no longer authorized by State law to engage in the . . . dispensing of controlled substances.'' With respect to

[1] The CALJ also cited *Odette L. Campbell,* 80 FR 41062, 41064 (2015), which he characterized as ''holding revocation proceedings in abeyance at the post-hearing adjudication level for a lengthy period pending the resolution of both criminal fraud charges and concurrent state administrative proceedings against the respondent.'' R.D. at 4. However, before the hearing was even held, Campbell allowed her registration to expire and she submitted an application only after she received a largely favorable decision from an ALJ. Thus, the matter did not involve a revocation, but rather, an application. Moreover, had Campbell been convicted of health care fraud, she would have been subject to mandatory exclusion from federal health care programs and her application would have been subject to denial on that basis.

[2] I also adopt the ALJ's ruling denying Respondent's motion for a stay of the proceeding. As for Respondent's contention that a stay of this proceeding ''would afford [him] with his due process right to be heard in a meaningful manner in the State . . . proceeding,'' Resp.'s Reply, at 2, the New Mexico Board has an obligation to provide him with Due Process regardless of whether a stay is granted in this proceeding. *See* U.S. CONST., amend. XIV, § 1. As for his further contention that if he ''prevailed . . . in front of the Medical Board, it would be contrary to due process considerations and judicial economy to . . . force [him] to reapply for his'' DEA registration, all DEA registrants (including those who have never been subject to a DEA Show Cause proceeding) are required to periodically reapply for their registration; he also provides no authority for the notion that there is a property interest under the Due Process Clause in not having to periodically reapply for a registration. I thus reject his contention that he was entitled to a stay.

[3] In accordance with the Administrative Procedure Act (APA), an agency ''may take official notice of facts at any stage in a proceeding-even in the final decision.'' U.S. Dept. of Justice, Attorney General's Manual on the Administrative Procedure Act 80 (1947) (Wm. W. Gaunt & Sons, Inc., Reprint 1979). In accordance with the APA and DEA's regulations, Respondent is ''entitled on timely request to an opportunity to show to the contrary.'' 5 U.S.C. 556(e); see also 21 CFR 1316.59(e). To allow Respondent the opportunity to refute the facts of which I take official notice, Respondent may file a motion for reconsideration within 15 calendar days of the date of service of this Order which shall commence on the date this Order is mailed.

a practitioner, DEA has also long held that the possession of authority to dispense controlled substances under the laws of the State in which a practitioner engages in professional practice is a fundamental condition for obtaining and maintaining a practitioner's registration. *See, e.g., James L. Hooper,* 76 FR 71371 (2011), *pet. for rev. denied,* 481 Fed. Appx. 826 (4th Cir. 2012); *Frederick Marsh Blanton,* 43 FR 27616 (1978).

This rule derives from the text of two provisions of the CSA. First, Congress defined ''the term 'practitioner' [to] mean[ ] a . . . physician . . . or other person licensed, registered or otherwise permitted, by . . . the jurisdiction in which he practices . . . to distribute, dispense, [or] administer . . . a controlled substance in the course of professional practice.'' 21 U.S.C. 802(21). Second, in setting the requirements for obtaining a practitioner's registration, Congress directed that ''[t]he Attorney General shall register practitioners . . . if the applicant is authorized to dispense . . . controlled substances under the laws of the State in which he practices.'' 21 U.S.C. 823(f). Because Congress has clearly mandated that a practitioner possess state authority in order to be deemed a practitioner under the Act, DEA has held repeatedly that revocation of a practitioner's registration is the appropriate sanction whenever he is no longer authorized to dispense controlled substances under the laws of the State in which he practices medicine. *See, e.g., Hooper,* 76 FR at 71371–72; *Sheran Arden Yeates,* 71 FR 39130, 39131 (2006); *Dominick A. Ricci,* 58 FR 51104, 51105 (1993); *Bobby Watts,* 53 FR 11919, 11920 (1988); *Blanton,* 43 FR at 27616.

Moreover, revocation is warranted even when a state board has resorted to summary process in suspending a practitioner's dispensing authority and the state has yet to provide the practitioner with a hearing to challenge the board's action. This is so ''because 'the controlling question' in a proceeding brought under 21 U.S.C. 824(a)(3) is whether the holder of a DEA registration '' 'is currently authorized to handle controlled substances in the [S]tate.' '' *Gentry Reeves Dunlop,* 82 FR 8432, 8433 (2017) (quoting *Hooper,* 76 FR at 71371 (quoting *Anne Lazar Thorn,* 62 FR 12847, 12848 (1997))); *see also Bourne Pharmacy,* 72 FR 18273, 18274 (2007); *Wingfield Drugs,* 52 FR 27070, 27071 (1987). Thus, it is of no consequence that the New Mexico Board has employed summary process in suspending Registrant's state license. What is consequential is that Respondent is no longer currently authorized to dispense controlled substances in the State in which he is registered.

In his reply to the Government's Motion for Summary Disposition, Respondent argued that the authority contained in 21 U.S.C. 824(a)(3) is a ''discretionary, not mandatory basis for revocation.'' Respondent's Reply, at 2. While Respondent cites *James Alvin Chaney,* 80 FR 57391 n.1 (2015), as support for his contention, footnote one of the Agency's Decision in *Chaney* addressed whether the respondent in that case had an active registration. Moreover, Respondent's contention that the Agency's sanction authority in cases involving a practitioner's loss of his state controlled substance dispensing authority remains discretionary, was squarely addressed and rejected in footnote 2 of the *Chaney* decision, as it has been in countless Agency decisions. *See Chaney,* 80 FR 57391 n.2; *see also, e.g., Charles Szyman,* 81 FR 64937, 64938 n.1 (2016); *see also Rezik A. Saqer,* 81 FR 22122, 22127 (2016); *James L. Hooper,* 76 FR 71371 (2011). And the Agency's rule has been upheld by two courts of appeals. *See Hooper* v. *Holder,* 481 Fed. Appx. 826, 828 (4th Cir. 2012) (''[b]ecause sections 823(f) and 802(21) make clear that a practitioner's registration is dependent upon the practitioner having state authority to dispense controlled substances, the [Administrator's] decision to construe section 824(a)(3) as mandating revocation upon suspension of a state license is not an unreasonable interpretation of the CSA''); *Maynard* v. *DEA,* 117 Fed. Appx. 941, 944–45 (5th Cir. 2004) (rejecting contention that DEA could not revoke practitioner's registration where state board's disciplinary panel ''merely temporarily suspended'' medical license ''without notice''). I will therefore order that Respondent's registration be revoked and that any pending application be denied.

Order

Pursuant to the authority vested in me by 21 U.S.C. 824(a), as well as 28 CFR 0.100(b), I order that DEA Certificate of Registration No.FB5001538, issued to John D. Bray-Morris, M.D., be, and it hereby is, revoked. Pursuant to the authority vested in me by 21 U.S.C. 823(f), I further order that any pending application of John D. Bray-Morris, M.D., to renew or modify his registration, or for any other registration in the State of New Mexico, be, and it hereby is, denied. This Order is effective immediately.[4]

Dated: July 27, 2017.

Chuck Rosenberg,

Acting Administrator.

[FR Doc. 2017–16446 Filed 8–3–17; 8:45 am]

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Marcia L. Sills, M.D.; Decision and Order

On January 21, 2015, the Deputy Assistant Administrator, of the then Office of Diversion Control, Drug Enforcement Administration, issued an Order to Show Cause to Marcia L. Sills, M.D. (hereinafter, Respondent). The Show Cause Order proposed the revocation of Respondent's DEA Certificate of Registration AS1456361, pursuant to which she is authorized to dispense controlled substances in schedules II through V, at the registered location of 2741 NE 34 St., Fort Lauderdale, Florida. GE 1, at 6. As grounds for the proposed action, which also includes the denial of any pending application for renewal and any other applications for new DEA registrations, the Show Cause Order alleged that Respondent's ''continued registration is inconsistent with the public interest.'' *Id.* (citing 21 U.S.C. 824(a)(4) and 823(f)).

With respect to the Agency's jurisdiction, the Show Cause Order alleged that while Respondent's registration was due to expire on February 28, 2014, she ''submitted a timely renewal'' application. *Id.* The Order thus asserted that her ''registration continues in effect pursuant to 5 U.S.C. 558(c).'' *Id.*

As for the substantive grounds for the proceeding, the Show Cause Order set forth numerous allegations that between November 2011 and July 2012, Respondent violated Florida and Federal controlled substances laws in her prescribing of controlled substances to an undercover officer and seven other patients. *Id.* at 6–10. With respect to the undercover officer, the Order alleged that on both May 31, 2012 and July 16, 2012, Respondent issued prescriptions to him for both oxycodone 30 mg, a schedule II controlled substance, and clonazepam, a schedule IV controlled substance, which were not for a

[4] For the same reasons that led the New Mexico Board to summarily suspend Respondent's medical license, I find that the public interest necessitates that this Order be effective immediately. 21 CFR 1316.67.

legitimate medical purpose in the usual course of professional practice under State and Federal law. *Id.* at 6–7. Specifically, the Order alleged, *inter alia,* that Respondent ''failed to conduct a sufficient physical exam,'' ''failed to provide a legitimate diagnosis,'' prescribed to the UC ''despite evidence that he had illegally obtained controlled substances,'' and had prescribed ''large quantities'' of oxycodone ''absent any reliable evidence that [the UC] had any tolerance to opioid medication and increased the quantities absent a legitimate medical purpose.'' *Id.* at 7. The Order also alleged that Respondent ''assisted the UC in his attempts to obtain controlled substances from a pharmacy without arousing suspicions that the prescriptions were issued for other than a legitimate medical purpose.'' *Id.* The Order thus alleged that Respondent violated both Federal and State law in issuing the oxycodone and clonazepam prescriptions. *Id.* (21 U.S.C. 829, 841(a); 21 CFR 1306.04(a) & 1301.71; Fla. Stat. Ann. §§ 455:44(3) & 456:072(1)(gg); Fla. Admin. Code r. 64B8–9.013).

The Show Cause Order also alleged that a medical expert who reviewed at least eight medical files of patients (including the undercover officer) treated by Respondent ''concluded that, in each case, [she] prescribed controlled substances to those patients without a legitimate medical purpose in the usual course of professional practice.'' *Id.* The Order specifically alleged that the expert found that Respondent ''distributed large amounts of controlled substances without conducting a sufficient medical history and/or physical examination and without determining the patients' tolerance to controlled substances,'' and did so ''even though the patients demonstrated evidence of drug abuse and/or diversion.'' *Id.* at 7–8. The Order then set forth detailed allegations regarding her prescribing to seven patients (other than the undercover officer), who presented such evidence. *Id.* at 8–9.

The Show Cause Order also notified Respondent of her right to request a hearing on the allegations, or to submit a written statement in lieu of a hearing, the procedure for electing either option, and the consequence for failing to elect either option. *Id.* at 10 (citing 21 CFR 1301.43). On February 2, 2015 the Government accomplished service by personally serving Respondent with the Show Cause Order. GE 26, at 4. (Declaration of Diversion Investigator (DI)).

On February 6, 2015, Respondent filed a motion for extension of the time to respond to the Show Cause Order on the ground that she had been charged in a criminal case based on ''essentially the same allegations and has maintained her [F]ifth [A]mendment right to remain silent pending trial'' and that she ''is not in a position to factually respond to this order until after her trial.'' Motion for Extension of Time Pursuant to 21 CFR 1316.47(b). Respondent further requested that the proceeding be ''abated . . . until the conclusion of the criminal matter.'' *Id.* On February 9, 2015, the Chief Administrative Law Judge (CALJ) denied the motion. Order Denying Resp.'s Motion for an Enlargement of Time to Respond to Order to Show Cause.

On February 19, 2015, Respondent filed a timely request for a hearing with the Office of Administrative Law Judges. In her request, Respondent ''denie[d] all of the factual assertions'' and legal conclusions of the Show Cause Order, and maintained that she ''did not violate any of the provisions argued by the [G]overnment.'' GE 20, at 1. However, on March 6, 2015, Respondent submitted a letter withdrawing her request for a hearing; the same day, the CALJ granted Respondent's request and terminated the proceeding. *Id.* at 3.

On October 13, 2016, the Government submitted its Request for Final Agency Action and an evidentiary record. Based on Respondent's letter withdrawing her request for a hearing, I find that Respondent has waived her right to a hearing. 21 CFR 1301.43. I therefore issue this Decision and Order based on relevant evidence submitted by the Government. I make the following factual findings.

Findings of Facts

Respondent is a physician licensed by the State of Florida. Respondent is also the holder of DEA Certificate of Registration No. AS1456361, pursuant to which she is currently authorized to prescribe controlled substances in schedules II–V, at the registered address of 2741 NE 34 Street, Fort Lauderdale, Florida. GE 1, at 1. In addition, she is authorized to dispense Suboxone and Subutex, pursuant to the Drug Addiction Treatment Act of 2000 (DATA), for the purpose of treating up to 30 opiate-addicted patients. *Id.; see* 21 U.S.C. 823(g)(2).

Respondent's registration was due to expire on February 28, 2014. While other agency records show that she submitted a renewal application on March 5, 2015, according to the Government, the ''renewal was marked received by the DEA mail room on March 1, 2014,'' and ''was likely received several days prior to March 1, 2014'' due to security screening measures. RFAA, at 1 n.1. Because Respondent's renewal was timely, I find her registration has remained in effect pending the resolution of this proceeding. *See* 5 U.S.C. 558(c). Government Request for Final Agency Action (RFAA), at 1.

At all times relevant to this proceeding (November 2011 to July 2012), Respondent was employed at the Pompano Beach Medical Center (PBM), located at 553 E. Sample Road, Pompano Beach, Florida. PBM was the subject of a criminal investigation which included undercover operations conducted on May 31 and July 16, 2012 by a former DEA Task Force Officer and Broward County Sheriff's Office Detective (hereinafter ''UC'') who posed as a patient at two medical appointments during which he was seen by Respondent, who prescribed various controlled substances to him.[1] GE 26, at 2.

During both visits with Respondent, the UC used audio and visual recording devices. *Id.* at 2–3. As part of the record, the Government submitted DVDs of the recordings as well as transcriptions of the recordings.[2] The Government also submitted copies of the prescriptions Respondent issued to the UC. GE 8, 10.

Following the UC's visits, the investigators obtained a state search warrant for PBM, and during the execution of the warrant, seized numerous patient files, including those of the UC and seven other patients. *Id.* at 4. The DI also obtained from various pharmacies copies of prescriptions which had been issued by Respondent to three of those patients. *Id.* Copies of the seven patient files and the prescriptions obtained by the DI are included in the evidence. *See* GE 12–18, 21, 23.

The Government's Expert

As part of its investigation, the Government retained Dr. Reuben M. Hoch, an Interventional Pain Medicine Specialist and Anesthesiologist, who reviewed the medical files, transcripts and recordings of the undercover officer's two visits with Respondent, as well as the patient files for seven other patients treated by Respondent. Dr.

[1] On August 16, 2012, Respondent was arrested and charged with two counts of Illegal Prescribing of Controlled Substances, two counts of Delivery of a Controlled Substance, one count of Racketeering, and one count of Conspiracy to Commit Racketeering. Declaration of DI, at 2 (citing Florida Statutes §§ 893.13(8)(a)(1) and (2), 893.13(1)(a)(1), 895.03(1) and (4)).

[2] The DI and the UC averred that true and accurate transcripts of the recordings were made and are provided in the evidence file, along with DVDs of the recordings. GE 25, at 5; GE 26, at 2–3. *See also* GE 3, 4, 5, 6, 7, 9.

Hoch received his medical degree from the Sackler School of Medicine at Tel Aviv University in 1988. GE 2, at 1. He has done an internship in internal medicine and both a residency in anesthesiology and a fellowship in pain management at New York University. *Id.* at 2. He is Board Certified in Anesthesiology and Pain Medicine by the American Board of Anesthesiology. *Id.* at 3.

Dr. Hoch, who is licensed in Florida and New York, currently practices pain medicine at Boca Raton Pain Medicine in Delray Beach, Florida, and previously served as the Chief of Multidisciplinary Pain Management Service in the Departments of Neurosurgery and Anesthesiology at The Brooklyn Hospital Center. *Id.* at 3–4. Dr. Hoch has served as an expert witness on approximately ten different occasions. *Id.* at 1. I find that Dr. Hoch is qualified to provide his expert opinion with regard to the prescribing practices of Respondent in her treatment of the UC and seven patients whose files he examined.

The Undercover Visits

On May 31, 2012, the UC presented at Pompano Beach Medical (PBM) and requested an appointment. GE 25, at 1 (Declaration of UC). The UC told the receptionist he had been working out of town for an extended period and had not been to PBM in the last five months.[3] *Id.* After the receptionist retrieved his file, the UC encountered the clinic's owner and told him that he had been out of town working; the owner then directed the receptionist to 'drug test' the UC. *Id.*

After the receptionist told the UC that the appointment would cost $230 plus $30 for the drug test, the UC made an appointment for later that day. *Id.* at 2. The UC returned later for his appointment and was drug tested. *Id.*

He also filled out various forms, including one titled: ''Patients [sic] Follow Up Sheet.'' GE 11, at 36. On the form, the UC circled the neck portion of a body diagram to indicate where he felt pain; according to the UC, he did so ''even though the MRI which [he] had previously provided to PBM was of [his] lower back.'' GE 25, at 2; *see also* GE 11, at 36. He also answered ''N'' (for no) to two questions: (1) ''Is the pain always there?'' and (2) ''Does the pain get worse when you move in certain ways?'' GE 11, at 36. In response to ''Has the pain affected any of the following: Social activities . . . Mobility . . . Work . . . Appetite . . . Exercise . . . Sleep?'' the UC circled ''Exercise.'' *Id.* He also noted that he had not been in any accidents since he had last visited PBM. *Id.*

On a numeric pain scale of 0–10, with 10 meaning ''hurts worst,'' [sic] the UC indicated the intensity of his pain as ''0'' ''with medication'' (''no pain'') and ''2'' ''without medication'' (''hurts little bit''). *Id.* Finally, he checked a printed statement stating ''I am *satisfied* with my current medication. I would *not* like to change it,'' and left unchecked the statement ''I am *not satisfied* with my pain medication and would like to discuss changes.'' *Id.* The UC then produced a urine specimen, had his weight and blood pressure recorded, and again spoke to the clinic owner, telling him that he had been in California where he had difficulty finding a pain clinic that would prescribe medications, and that it had been difficult to find pharmacies to fill prescriptions for oxycodone. GE 25, at 2 (UC's Declaration). According to the Drug Screen Results Form, which lists numerous controlled substances including ''Opiates/Morphine,'' ''Benzodiazepine[s],'' and ''Oxycodone,'' the UC tested negative for all drugs. GE 11, at 39.

The UC then met with Respondent, telling her that he was a film stuntman who often travelled, that he had been away for work and just returned, and that he had ''stiffness in [his] lower back and . . . neck.'' GE 7, at 1–2 (Transcript of May 31, 2012 visit). Respondent asked the UC how long it had been going on, and UC told her he had seen ''five . . . I think, six doctors'' and ''so I have a lot of times I have the stiffness . . . [u]mm aches.'' *Id.* at 2. He then stated ''two or three'' years, and when Respondent asked: ''It wasn't a car accident or anything?'' UC replied: ''No, no, no it's actually, no critical injury at all. It's you know muscle soreness from the work that I do.'' *Id.* at 3; *see generally* GE 3, V–0002, at 14:10:54–14:13:30.[4]

Respondent, reading paperwork, then asked the UC a series of questions, including whether he had a lockbox or safe to keep medicine in (telling him he should get one when he responded ''no''), whether he had little kids living with him, if he was on disability, and whether he had ''any problems with sleeping or anxiety?'' GE 7, at 3. The UC replied: ''Once in a while. I used to take a little bit of Xanax to sleep, but I think I can probably work without it.'' *Id.* Respondent stated: ''Okay if you need anything to relax you for anxiety we use Klonopin instead of Xanax''; UC replied ''Okay, I'll try it, sure.'' *Id.* Respondent checked both ''anxiety'' and ''insomnia'' in the Pain History section of the visit note. *Id.; see also* GX 3, V–0002, at 14:13:30–14:14:00; GE 11, at 3.

Respondent, who was still reading the form, then asked the UC if he had ''seen another pain management doctor in 28 days?'' UC responded ''No.'' GE 7, at 3. *Id.* Next, Respondent asked: ''Your quality of life is better with than without the medicine I assume?'' to which the UC replied ''Yes.'' *Id.* Respondent circled and/or checked the corresponding items on the form. GE 3, V–0002, at 14:14:00–14:14:08; GE 11, at 33.

After asking about recent hospitalizations, chest pains, shortness of breath or cardiac problems, Respondent asked the UC if he ''kn[ew] the risks of the medicine, addiction, overdose, death, damage to your liver or kidneys?'' GE 7, at 3–4. Without waiting for a reply from the UC, Respondent added that ''we have your blood work to check your liver and kidneys and I'll look at your MRI too.'' *Id.* at 4; GE 3, V–0002, at 14:14:08–14:14:24.

Respondent then asked UC to stand up ''carefully . . . let me see how you can bend forward.'' *Id.* UC responded: ''I'm pretty . . . from what I do.'' GE 7, at 4. The video recording shows that the UC stood up, turned to move his chair, and immediately bent down, touched his hands to the floor and straightened back up again. GE 3, V–0002, at 14:14:24–14:14:35. In his Declaration, the UC states he ''quickly touched my hands to the floor without hesitation or pain.'' GE 25, at 2.

After asking the UC his age, Respondent asked: ''[I]s your neck okay? . . . Good range of motion in your neck?'' GE 7, at 4. UC, shook his head left to right, and replied: ''Yeah I feel more stiffness when I do, you know, like I do heavy squats. Things like that. That's when I usually have those feelings.'' *Id.* Respondent asked if UC had numbness or tingling in his legs, which he denied, asking ''that would be bad, wouldn't it?'' *Id.* Respondent explained ''it means you might have a herniated disc that's you know pinching.'' *Id.; see also* GE 3, V–0002, at 14:14:35–14:15:03.

Respondent, while looking through paperwork, then stated: ''so these labs are okay. And I want to look at your MRI.'' GE 7, at 4. After briefly looking at the MRI, Respondent stated: ''[n]othing too terrible . . . I don't see any herniated discs,'' and while noting that he had a bulging disc, she added:

[3] The TFO, in his undercover capacity, had last visited PBM in January, 2012, and, prior to that from May–September 2011, when he was treated by different physicians.

[4] Due to the length of the citations to the videos, all such citations are provided at the end of each paragraph.

''a bulge kind of doesn't mean anything. You've got spasms.'' *Id.; see also* GE 3, V–0002, at 14:15:03–14:15:27.

Continuing, Respondent stated: ''we don't give narcotics for spasms . . . [a]nd we don't give [S]oma. I will give you another muscle relaxant.'' GE 7, at 5. Respondent added: ''[a]nd if you want something instead of Valium I'll give you something for that too.'' *Id.* UC responded ''Okay.'' *Id.;* GE 3, V–0002, at 14:15:27–14:15:41.

Respondent then told UC that Klonopin, ''like Valium and Xanax, is for anxiety. And the reason why people take it at night is to reduce anxiety so they can sleep. It is not a sleeping pill.'' GE 7, at 5. She added: ''so Klonopin is long acting unlike Valium and Xanax which are short acting benzos [sic] every 3 to 4 hours, Klonopin is 12 to 24.'' *Id.* When UC asked ''When will I take it, at night before bed?'' she responded: ''It's up to you . . . [n]ight time before bed . . . [b]ut it's not going to zonk you out and it won't give you fogginess. It brings down anxiety a bit.'' *Id.* The UC responded ''Okay.'' *Id.;* GE 3, V–0002, at 14:15:41–14:16:16. According to the UC, in all of his prior visits to PBM, he ''never disclosed that [he] suffered from anxiety.'' GE 25, at 3.

Respondent, looking at the UC's file, then returned to discussing the UC's MRI, stating: ''[o]kay so there's a bulge which by itself it wouldn't mean anything . . . [b]ut I'm gonna make a note here . . . the one up from your tailbone L4,5 . . . it has a small tear in the end which means that due to trauma, something was, the disc was trying to herniate and didn't quite make it . . . and also there is a little bit of pushing of the nerve . . . very little . . . but it is there.'' GE 7, at 5–6. The UC interjected with ''Okay'' sporadically throughout Respondent's discussion. *Id.; see also* GE 3, V–0002, at 14:16:16–14:16:51.

Respondent then asked the UC: ''[h]ow much Roxicodone were you taking? We don't do 120. What were you taking four or five a day? Tell me.'' GE 7, at 6. The UC responded ''[y]es,'' and Respondent asked: ''About four a day? Okay we're good for that. And . . . the Klonopin, I'm going to give you a milligram. . . . I'm also gonna give you some ibuprofen. Because if your [*sic*] filling in Florida which I encourage you to so you're on the computer list. Then . . . for two reasons: number one, the pharmacists usually want a non-prescription drug, a non-controlled substance drug rather . . . and ibuprofen is also good for inflammation.'' *Id.* UC responded with ''Gotcha'' and ''Okay.'' *Id.* Respondent continued: ''If you need something to relax your muscles . . . Let me give you some Flexeril. It's cheap and it works.'' *Id.;* GE 3, V–0002, at 14:17:10–14:18:15. Notably, Respondent had not even performed her physical exam prior to agreeing to prescribe the controlled substances to the UC.

As the video shows, only after she discussed the dosing of Flexeril, did Respondent leave her desk chair and approach the UC, who stood up. According to the UC, Respondent ''asked me to stand up again, placed a stethoscope on my chest for approximately two seconds, and asked me to sit.'' GE 25, at 3 (UC Declaration). While the video feed was blocked during that action, the audio reveals that Respondent told UC a story about a former patient and that she did not stop talking during the time she placed the stethoscope on the UC's chest. She then had him sit, and, according to the UC, ''squeezed my calves while asking if he had any tenderness here?'' *Id.* UC replied ''no.'' GE 7, at 7. Again she asked: ''[a]ny tenderness here?'' *Id.* UC replied ''No.'' *Id.; see also* GE 25, at 6. According to the UC, Respondent ''also struck my knees with a neurologic hammer to test my reflexes even though my feet still were planted on the floor.'' GE 25, at 3; GE 3, V–0002, at 14:18:15–14:19:25. As the video shows, the tests Respondent performed totaled less than one minute. *See generally* GE 3, V–0002, at 14:14:24–14:14:35 and 14:18:34–14:19:18.

After some unrelated discussion, Respondent asked the UC how often he came back, to which he replied ''I'll come every 28 days.'' GE 7, at 8. She then asked: ''[d]o you try to spread your medicine out if you don't have it?''; the UC replied: ''[y]eah well I do the best I can with what I have.'' *Id.* Respondent told the UC: ''[y]ou know the Roxicodones, this is the short acting. It's safe to break in half.'' *Id.* UC then asked: ''Gonna be thirties still?'' *Id.* Respondent replied: ''[t]hirties'' and added ''[w]e only give thirties.'' *Id.* Respondent then advised the UC to use a pill cutter and told him that ''the ones you can't break in half are the long acting. Because if you break them in half . . . the ones that they call (inaudible) you can overdose''; the UC said ''Okay.'' *Id.* Respondent added: ''all the people that break them in half they're using them for the bad purposes and they don't overdose because their body is so addicted, so.'' *Id.* After the UC stated ''right,'' Respondent added: ''I'm not allowed to say that.'' *Id.;* GE 3, V–0002, at 14:19:38–14:20:28.

Respondent then asked the UC if he ''had a pharmacy that would honor [his] prescriptions.'' GX 25, at 3; GX 7, at 8. The UC told her that ''last time I had a problem. And I actually . . . a friend . . . sent me to an online pharmacy . . . and I sent them and they sent them back I think it was in Georgia.'' GX 7, at 9. Respondent told him ''I would highly recommend not doing that anymore in Georgia because DEA is looking at things across the states. If you can find an online pharmacy . . . okay, a lot of them have been shut down since you've been here.'' *Id.;* GE 3, V–0002, at 14:20:28–14:21:00.

The UC then asked if there ''are any pharmacies that are known to the facility here that are pretty . . .?'' and Respondent replied: ''let's ask them in the front.'' GX 7, at 9. Respondent stated that she ''can't recommend one. They know who goes to where. If you have a relationship with one I then was gonna [sic] encourage you to go back . . . that's your best bet.'' *Id.* The UC told Respondent that when he ''tried to go there, they were out . . . and when I last went there, you know what they were telling me . . . a lot of people are moving to Dilaudid because the oxys are so short.'' *Id.* Respondent replied: ''[t]rue and the Dilaudid is getting short so then they moved to short acting morphine.'' *Id.* Respondent then stated: ''[s]o here's the deal, if you can't find this within a week, um anytime within a week . . . giving it a good college try, come back free and I'll swap it.'' *Id.;* GE 3, V–0002, at 14:20:00–14:21:48.

Respondent further told the UC what days of the week she was at the clinic, prompting him to ask: ''[w]hat would you recommend? If it wasn't the oxycodone, morphine or Dilaudid?'' GE 7, at 9. Respondent replied: ''I would go with the Dilaudid myself.'' *Id.* After summarizing her prescriptions to the UC, and a brief discussion of how and when to take the new prescriptions, she asked him if he had any allergies, to which he replied ''no,'' and the office visit ended. *Id.* at 9–10; GE 3, V–0002, at 14:21:48–14:22:52.

Respondent wrote the UC prescriptions for 112 tablets Roxicodone (oxycodone) 30 mg ''for pain,'' 28 tablets Klonopin (clonazepam) 1 mg ''for anxiety,'' 56 tablets Ibuprofen 400 mg, and 28 tablets Flexeril 10 mg. GE 8 (copies of prescriptions); GE 11, at 32 (Encounter Summary). A report in the UC's file shows that he filled the Roxicodone prescription on June 5, 2012 at Coral Springs Specialty Pharmacy in Coral Springs, Florida. *Id.* at 22. An unsigned and undated handwritten note on the report page asks ''Where is patient filling? Or did he have different address in past?'' *Id.*

The UC's file includes a three-page visit note signed by Respondent on May

31, 2012. GE 11, at 33–35. The first page lists the UC's name, date of the visit, and vital signs, below which is a section titled: ''Pain History Follow Up''; this section includes various words to circle and fill-in-the-blank statements which correspond to the questions Respondent asked UC during the visit.[5] *Id.* at 33.

On the form, Respondent circled ''back'' and ''lower'' as the location of UC's pain, noted the ''Duration of pain'' as ''3 yr[s],'' and that the ''Severity of Pain'' was ''severe'' (as opposed to ''mild'' or ''moderate''). *Id.* at 33. Under ''precipitating event,'' she wrote ''unknown'' with ''work—stuntman'' handwritten nearby. *Id.* Under ''character of pain,'' she checked ''throbbing'' and ''sharp,'' and listed ''anxiety'' and ''insomnia'' as ''Co-morbidities.'' *Id.*

The form also contains blanks for noting the UC's ''Pain Scale off meds (0–10)'' and ''on meds.'' *Id.* In the blank for ''off meds,'' the form contains the scratched-out number ''2,'' followed by the number ''5''; in the blank for ''on meds,'' the form states ''0''. *Id.* As for the blanks regarding the UC's quality of life both off and on medications, Respondent checked ''worse''' for ''OFF medications'' and ''better'' for ''ON medications.'' *Id.* After ''New Events Since Last Visit'' she wrote ''stuntman for movies—was in Cal. Last here Jan 18, 2012.'' *Id.*

The form's first page also contains a checklist for ROS (Review of Systems), on which Respondent checked: ''All negative unless checked.'' *Id.* This page also includes a section captioned with ''PE'' (physical exam), which list various exams items. *Id.* In this section, Respondent drew check marks and diagonal lines through various findings to include: (1) ''HEENT'' (head, eyes, ears, nose and throat), with check mark through ''inspection wnl,'' (2) ''Chest,'' checkmark through ''clear,'' (3) ''Cor,'' diagonal line draw through ''rrr,'' (4) ''Abd,'' diagonal line drawn through ''soft, non tender,'' (5) ''Skin,'' diagonal line through ''wnl, no rash,'' (6) ''Ext,'' line drawn through ''nontender, full ROM,'' (7) Neuro/psych, with checkmark drawn through ''Ox3,'' and (8) ''Gait,'' with a check mark drawn through ''normal.'' *Id.*

The form also includes four diagrams of the human body, including a posterior view; on this diagram, Respondent circled the neck and noted ''ROM WN,'' circled the lower back and noted ''Flex 90 Ext 10,'' and circled the back of the knees and noted ''reflexes =.'' *Id.* She also noted on this page that the UC's UDS (urine drug screen) was negative ''today.'' *Id.*

The form's second page included entries for a Neurological exam. *Id.* at 34. Respondent checked ''yes'' for each item which included: ''Cranial Nerves: II–XII intact,'' ''Sensory Exam: Gross wnl to light touch,'' ''Reflexes +2 bilateral and symmetric upper ext'' and ''+2 bilateral and symmetric lower ext,'' ''Muscle Strength: bilat upper and lower.'' *Id.* Respondent also circled ''−,'' this noting that the UC had a negative straight leg raise with respect to both his right and left legs. *Id.*

Under ''Assessment,'' Respondent made marks next to the following entries:

> Patient satisfied, doing well on current medication and treatment plan; pain condition stable.
>
> Patient taking meds as prescribed and no adverse side effects, no new problems and no changes;
>
> Denies any drug charges or arrests since last visit;
>
> Medication storage and safety issues addressed and patient uses lock box; Diagnosis and treatment plan are justified and based on diagnostic results, history and physical exam.[6]
>
> *Id.*

Under ''Diagnosis, Respondent checked ''Anxiety,'' ''Disc Bulge,'' ''Muscle Spasms,'' ''CHRONIC NON-MALIG PAIN SYNDROME,'' and ''Other,'' after which she made a handwritten note stating: ''L45 Bulge tear annular Bilat neural foraminal encroachment.'' *Id.*

Under ''Plan,'' Respondent made lines through multiple entries. These included: (1) ''wt loss, smoking cessation, reduce salt and caffeine, F/U with PCP''; (2)'', ''refer to PT, neurologist, neurosurgeon, orthopedist, psychiatrist, addiction specialist as needed''; (3) ''F/U in one month to follow the success of treatment and need for adjustments''; (4) ''Patient understands importance of weaning meds to minimum effective dose''; (5) ''Yoga, stretching exercises; Fish oil at 3–6 grams/day; glucosamine/Chondroitin Sulfate as suggested''; (6) ''Discussed informed consent, risks/benefits of given medications, alternate therapies; pt understands''; and (7) ''Continue meds,'' followed by for a second time, ''patient understands importance of weaning meds to minimum effective dose.'' *Id.* Respondent did not, however, place a checkmark next to the entry for ''urine tox screen twice a year or as needed to monitor addiction/diversion.'' *Id.*

The third page includes a pre-printed list of both controlled and non-controlled drugs. Of note, the only narcotic listed on the pre-printed form is Roxicodone in the 30 milligram dosage form, next to which the form contains the pre-printed notations of ''#84 #112 #140 #168,'' with ''#112'' circled on the UC's form. *Id.* at 35. Respondent also checked the box for Klonopin, circling the dosage of ''1 mg'' and the ''#28,'' as well as the boxes for the non-controlled drugs, Flexeril and Ibuprofen 400 mg #56. *Id.*

On checking out, PBM's receptionist provided the UC with the four prescriptions. GE 25, at 3. She also provided him with an appointment card, which listed his next appointment as scheduled for June 28, 2012. *Id.*

In his declaration, the UCs stated that at no time during his visit with Respondent did she inquire ''about any past treatments for pain other than to note what other doctors at PBM had prescribed, that there was no inquiry into any underlying or coexisting diseases or conditions, the effect of pain on my physical and psychological function, or whether I had any history of substance abuse.'' GE 25, at 5.

On July 16, 2012, the UC returned to PBM. *Id.* at 3. *See also generally;* GE 5 V–0003 (video recording). On the ''Follow-Up Sheet,'' the UC again circled the neck region of a body diagram to show where he felt pain. GE 11, at 29. He also circled ''N'' for no in answer to the questions: ''Is the pain always there?'' and ''Does the pain get worse when you move in certain ways?'' *Id.*

Another question on the form asked: ''Has the pain affected any of the following: Social Activities, Work, Exercise, Mobility, Appetite, Sleep.'' *Id.* The UC circled none of these. *Id.* The UC also indicated that intensity of his pain was ''0'' ''With Medication'' and ''1–2'' ''Without Medication,'' ''1–2.'' *Id.* However, the UC also checked the statement: ''I am *not satisfied* with my

[5] During the office visit, the video shows Respondent filling out the form, which lists various items which were either circled or had a place for providing a checkmark: Location of Pain: Neck, Back (upper mid lower) Radiation ____ Head Face Chest Abdomen, R/L: Shoulder F-arm Elbow Arm Wrist Hand Hip Thigh Leg Knee Ankle Foot, Duration of Pain ____ Severity of pain ____ mild ____ moderate ____ severe, Precipitating Event ____ MVA ____ Fall ____ Accident ____ Other ____ Unknown, Character of Pain __ throbbing __ sharp __ dull __ tingling Comorbidities __ anxiety __ insomnia __ other, Lock Box __ Y __ N Kids __ Y ___ Ages __ N Pysch Visits/SS Disability past 5 yr ___ Y___ N, Have you seen another Pain Management Doctor in the past 28 days? ___Y ___N, Pain Scale off meds (0–10) ____ Pain Scale on meds (0–10) ____, Quality of life OFF medications __ better __ worse / Quality of life ON medications __ better __ worse, New Events Since Last Visits _____, GE 11, at 33.

[6] Respondent did not, however, make a mark next to the entry for ''Activities of living, quality of life improved with medication.'' GE 11, at 34.

medication and would like to discuss changes.'' *Id.*[7]

After greeting the UC, Respondent asked him when he had last been to the clinic, to which the UC replied that he was two weeks late and offered the explanation that Respondent was gone the first week and then had a job out of town. GE 9, at 1–2. Respondent then spent several minutes preoccupied with a cellphone text message, after which she asked him a series of questions because the clinic had redone ''all the forms'' since his last visit. *Id.* at 2–4. While making notations on paperwork at her desk, Respondent asked: ''[t]hrobbing, sharp, dull, what would you say?'' *Id.* at 4. The UC replied ''No, no just you know like I said that muscle soreness is the best way I can say it.'' *Id.; see also* GE 5, V–0002, at 15:32:10–36:21, V–0003, at 15:36:30–15:36:41.

Respondent then asked the UC ''no disability, no rehab, no addiction?'' to which the UC answered ''no,'' followed by whether he had ever ''ha[d] surgery for [his] back?'' and ''physical therapy, injections?,'' with the UC answering ''no'' and ''nope.'' GE 9, at 4; GE 5, V–0003, at 15:36:30–15:36:48.

Respondent said, ''Okay, just the meds. You haven't seen anyone else in the past 28 days?'' GE 9, at 4. UC replied ''No.'' *Id.* GE 5, V–0003, at 15:36:48–53.

Next, Respondent asked the UC for his pain level ''[o]ff medicine . . . on a scale of ten to zero.'' GE 9, at 4. After the UC replied: ''[o]ff medicine, two,'' Respondent looked up from her desk at him and demonstrated a line on the desk, explaining, ''Okay, ten is the worst . . . zero is perfect. Without medicine it would be closer to ten.'' *Id.* at 4–5. UC replied: ''Okay, uh, what probably, I'm not sure, on the pain scale . . . four or five? Is that better?'' *Id.; see also* GE 5, V–0003, at 15:36:53–15:37:17.

Respondent then asked ''Okay and then with medicine?'' to which UC replied ''Zero?'' GE 9, at 5. Respondent stated that she was not ''not trying to you know,'' prompting the UC to state that he ''totally underst[ood],'' after which Respondent explained that ''I have to go over this each time. . . . Pain worse lifting, bending, sitting, standing?'' *Id.* UC replied: ''Working out. You know just once in a while when I'm done working out.'' *Id.;* GE 5, V–0003, at 15:37:17–15:37:33.

Respondent asked: ''What makes it better? Lying, resting, ice, heat, massage?''; the UC replied: ''I don't really do any of those things, so it's you know, like I said, it's just'' before Respondent interjected by stating ''Meds'' and asked ''does the pain affect your work, sleep, mood, etc?.'' GE 9, at 5. *Id.* UC answered ''No,'' prompting Respondent to ask: ''[w]hat does the pain affect in your life?'' to which Respondent replied: ''my recovery time from working out for sure.'' *Id.;* GE5, V–0003, at 15:37:33–15:37:52.

Respondent replied ''Okay. Uh, well we certainly wouldn't just give pain medicines and narcotics so your [sic] working out is better,'' to which UC replied, ''No, no, no I understand, I understand.'' GE 9, at 5. The following exchange then ensued:

> Respondent: ''So does the pain affect anything else in your life?''
> UC: ''What are the options again?''
> Respondent: ''Work'' (stated slowly and emphatically).
> UC: ''Let's say work.''
> Respondent: ''Sleeping.''
> UC: ''Work.''
> Respondent: ''Relationships.''
> UC: ''Work.''
> *Id.* at 5–6; GE 5, V–0003, at 15:37:52–15:38:14.

Next, Respondent asked the UC if his ''quality of life [is] better with medicine than without?''; UC answered ''sure.'' GE 9, at 6. Respondent then stated: ''Otherwise you shouldn't be on the medicine,'' to which the UC replied ''right.'' *Id.* Respondent also asked the UC, ''no blood pressure, diabetes, nothing else?'' and if he drank or smoked. *Id.* UC denied all but ''drink[ing] socially but very rarely'' and having ''a cigar occasionally but that's about it ever.'' *Id.;* GE 5, V–0003, at 15:38:14–15:38:37.

After Respondent and the UC discussed at length whether he needed to obtain a lockbox or safe for his medicine to protect it from being stolen, Respondent looked at the UC's MRI and stated: ''there was some muscle spasm there . . . bulges we don't treat. But your bulges have . . . what we call encroachment or it had narrowing of the disc in that area . . . which is kind of rare . . . I better put that down.'' GE 9, at 8; GE 5, V–0003, at 15:38:37–15:42:13.

Respondent then asked UC ''so you satisfied with the medicine?'' GE 9, at 9. UC told her that he thought she ''took me down just a little bit less from the last doctor which is no big deal but the two weeks off . . . definitely, definitely ran out of medication so.'' *Id.* After Respondent interjected ''oh its gotta be,'' the UC stated: ''my friend had some. So I was able to just hold me over until now.'' *Id.* Respondent nodded her head in agreement while the UC was talking and stated ''which we try not to do.'' *Id. See generally* GE 5, V–0003, at 15:42:13–15:42:53.

UC then told Respondent that from the list of seven pharmacies he had obtained from PBM at his previous visit, the seventh pharmacy filled the prescriptions. GE 9, at 9. The UC further stated that: ''[t]he first six said no or they didn't have it. The problem was that the last one is, the pharmacist said 'I can fill the oxycodone, I can fill the ibuprofen, and I can fill the . . . other . . . I don't even remember what the other one was to t[ell] you the truth.'' *Id.* Respondent looked at the chart and said, ''Roxicodone, Klonopin,'' and the UC told Respondent that the pharmacist told him ''she wouldn't fill the clonazepam'' and handed the prescription back to him, stating that she didn't ''feel comfortable filling'' it even though she had called and verified that the prescription was okay. *Id.;* GE 5, V–0003, at 15:42:53–15:43:29.

Respondent noted that ''Xanax is five times more dangerous than Klonopin,'' and the video shows that Respondent threw her hands in the air and stated: ''I don't understand this . . . this is a low dose. That is the first time I heard that.'' GE 9, at 9. UC told her that the pharmacist told him to go fill it somewhere else, to which Respondent replied: ''[t]hat's a cuckoo pharmacist.'' *Id.* at 10. UC told Respondent he didn't fill it because he didn't want to get her or Steve (the clinic owner) in trouble, but ''like I said my buddy just had a couple of Xanax and that was it.'' *Id.;* GE 5, V–0003, at 15:43:29–15:44:05.

Respondent the told the UC to ''[g]o take it to another pharmacy. That's not doctor shopping.'' GE 9, at 10. Continuing, Respondent stated: ''I want you to know doctor shopping is if you take more than one doctor . . . my prescription and another doctor to one or more pharmacies in 28 days. But if somebody refuses to fill a legitimate prescription you can go to another pharmacy. Try to go close to the same day so it all comes out the same.'' *Id.;* GE 5, V–0003, at 15:44:05–15:44:27.

Respondent then told UC she would ''write that and I'll write another non-narcotic. She's gonna [sic] fill Roxicodone but she won't fill one milligram of Klonopin?'' GE 9, at 10. The UC told Respondent that the pharmacist ''said she wouldn't fill the oxycodone without the other ones

[7] Another document in the UC's medical file bears the caption ''June ___ 2012 Audit Page Patient name'' with his undercover name printed. GE 11, at 31. The sheet includes the note: ''Intake 5/7/11—shoulder surgery 2002'' and that an MRI was received on ''5/12/11—Lumbar.'' *Id.* It also lists UDSs as having been done on both ''5/17/11'' and ''5/31/12'' and that both were ''negative,'' as well as his ''B/P'' and Pulse at various visits. *Id.* While the sheet also includes the note ''stuntman travels frequently for job in CA,'' the sheet is blank in the spaces for ''referral out,'' ''records ordered'' and ''records received.'' *Id.* Indeed, the file contains no medical records from other physicians.

either'' and ''I'm like okay. No. Fine. Fill them,'' and Respondent told the UC to ''[g]et another place.'' *Id.;* GE 5, V–0003, at 15:44:27–15:44:40.

UC stated that this was the reason he ''was sending them out to Georgia and getting them sent back,'' to which Respondent replied: ''If you're gonna do that then I have to have proof that you're getting them filled. . . . The reason why we have the state law is so we can track the narcotics . . . the medicines and if they go to Georgia we can't track them in Florida.'' GE 9, at 10–11. After the UC told Respondent he had ''filled the last ones here,'' Respondent told the UC that if he ever ''filled out of state . . . get us a paper copy . . . the exact medicines, the dosage and the date.'' *Id.* at 11; GE 5, V–0003, at 15:44:40–15:45:19.

After re-iterating that it was not doctor shopping for the UC to take the Klonopin prescription to another pharmacy, Respondent asked him to ''stand up . . . and let me see how you're bending.'' GE 9, at 11.[8] The UC stood up, bent his torso towards the floor and back up. Respondent listened to UC's back with a stethoscope and appeared to move his head, and asked ''Any pain going back?'' and ''No pain here?'' with the UC answering ''no'' to both questions. *Id.* at 12; *see also* GE 5, V–0003, at 15:45:19–15:46:22.

Respondent then told the UC to sit down and face her, and after he sat down, Respondent appeared to lift one leg straight out and then the other, asking ''Any pain in your back?'' GE 9, at 12. The UC replied: ''I'm just . . . my legs are just tight, tight, tight. I just did legs. My hamstrings feel like they're gonna light up.'' Respondent replied ''I'm talking about your back'' and UC replied ''No.'' *Id.;* GE 5, V–0003, at 15:46:22–15:46:47.

At this point, Respondent returned to her desk. As the video shows, the entire physical exam lasted just over one minute, during which the UC was never put in the supine position. GE 5, V–0003, at 15:45:36–15:46:47.

The UC then told Respondent that ''most problematic thing is when I do squats . . . . heavy squats'' and this is ''when I can feel the majority of any kind of stiffness in my back[,] but right now it feels good.'' GE 9, at 12. The UC then asked Respondent if he should ''have surgery for that tear,'' with Respondent stating that she ''wouldn't recommend it'' and then asked if his pain ''seem[ed] to be worse on one side versus the other.'' *Id.* The UC said ''no,'' and asked ''will it get worse gradually or no?'' *Id.* Respondent replied that the UC did not have ''a clear cut hernia,'' but that the condition would not heal by itself and ''might eventually develop into a hernia.'' *Id.* However, after the UC mentioned that his father ''had seven hernias,'' and that ''like three of them were repairs,'' Respondent clarified that she was ''talking about'' the UC's ''spinal column'' and herniated discs. *Id.* at 12–13; GE 5, V–0003, at 15:46:48–15:47:59.

After a short discussion of her having been ''away for a couple of days,'' Respondent, in an apparent reference to the quantity of the UC's next oxycodone prescription, stated: ''Alright let's go to one forty,'' prompting the UC to say ''okay,'' after which Respondent added: ''I can't justify more than that.'' GE 9, at 13; GE 5, V–0003, at 15:48:00–15:48:29.

While writing the prescription Respondent again was distracted by a cell-phone text message, which she returned before repeating: ''Okay so we're gonna [sic] go up to one forty . . . any side effects you let me know about. And I'm gonna write for Klonopin again.'' GE 9, at 13–14. After another brief discussion of why the pharmacist had refused to fill the previous Klonopin prescription with Respondent stating that the Klonopin ''is a very good match with oxycodone and doesn't potentiate the side effects of oxycodone,'' Respondent told UC she was going to give him two non-narcotic prescriptions so he could ''get them filled someplace else.'' *Id.;* GE 5, V–0003, at 15:48:29–15:50:25.

The UC and Respondent then discussed the street price of oxycodone, during which UC stated that ''you can buy them on the street for [13] dollars,'' prompting Respondent to state: ''[n]o, [y]ou can't buy them on the street for [13] dollars'' and that the price was ''at least double'' or ''triple.'' GE 9, at 14–15; GE 5, V–0003, at 15:50:25–15:50:53.

The UC explained that he knew that oxycodone was ''going for a lot of money up in Tennessee and places like that'' and that ''it's just crazy when you spend over a thousand dollars for a prescription''; Respondent stated: ''but they'll fill the Roxicodone. I mean, I'm just flabbergasted.'' GE 9, at 15. After the UC stated that he was also ''taken back by that,'' Respondent stated: ''[t]his is gonna be [140] for the pain. . . . How can a pharmacist . . . they'll fill the oxycodone . . . but they, I promise you there was another reason why that wouldn't fill it. There had to be another reason.'' *Id.* The UC told Respondent that ''it was a name of a pharmacy they gave me here,'' and after the UC reminded Respondent that the pharmacist had said that she did not ''feel comfortable filling this drug,'' Respondent stated that that was ''a cover.'' *Id.;* GE 5, V–0003, at 15:50:53–15:51:54.

Respondent then told the UC that she was giving him ''two small'' ''non-narcotic'' prescriptions for ''twenty-eight'' ibuprofen ''for each pharmacy that you might have to go to.'' GE 9, at 15–16. She then told Respondent that ''there's nothing to say if you went back to the same pharmacy . . . that another pharmacist wouldn't even bat an eyelash . . . because there's nothing to bat an eyelash over.'' *Id.* at 16; GE 5, V–0003, at 15:51:54–15:52:50.

Respondent then prepared on a computer prescriptions for 140 oxycodone 30 (''for pain'') and 28 Klonopin 1 mg (''for anxiety''), telling him to ''hold onto the Klonopin. If they won't fill it just take it.'' GE 9, at 16; *see also* GE 25, at 5. She also told the UC that ''I want you to keep the extra ibuprofen so if they won't fill the Klonopin again . . . you have another non-narcotic to use,'' and asked the UC: ''[m]ake sense?'' GE 9, at 17. The UC stated that ''it does make sense,'' and after an exchange of pleasantries, Respondent personally handed the UC one of the ibuprofen prescriptions and the visit with Respondent ended. *Id.;* GE 5, V–0003, at 15;52:50–15:53:45. Subsequently, a medical assistant handed the other prescriptions to the UC as well as an appointment card for his next visit. GX 25, at 5.

In addition to the oxycodone and Klonopin prescriptions, Respondent provided the UC with a prescription for 28 Flexeril 10 mg ''for muscle spasm,'' and two prescriptions for 28 ibuprofen 400 mg. GE 10, at 1–5; *see also* GE 11; at 23 (July 16, 2012 Encounter Summary). Of note, the oxycodone prescription lists five different diagnoses: ''Insomnia due to Medical Condition,'' ''Chronic Pain Syndrome,'' ''Lumbar Disc Displacement Without Myelopa,'' ''Lumbar or Lumbosacral Disc Degeneration,'' and ''Lumbago.'' GE 10, at 1.

In the UC's patient file for the July 16, 2012 visit, Respondent noted the lower back as the location of UC's pain, that the duration of his pain was three years, and checked the box indicating that his pain was ''severe.''' GE 11, at 25. As for the precipitating event, Respondent checked the box for ''unknown'' and wrote '''work-stunt man.'' *Id.* As to the character of his pain, she placed checkmarks next to ''throbbing'' and ''sharp''; she also made markings indicating that ''anxiety'' and ''insomnia'' were comorbidities. *Id.*

Respondent wrote the word ''meds'' to indicate his ''previous pain

[8] Respondent asked the UC to stand up and bend at 15:45:36 of the video.

management treatment.'' *Id.*[9] She also noted that ''off meds'' his pain was a ''5'' on a ''0–10'' scale, and ''on meds,'' his pain was ''0.'' *Id.* As to what made the UC's pain worse, Respondent checked ''lifting,'' ''bending,'' ''sitting, standing in one position too long,'' and ''other,'' after which she wrote ''working out.'' *Id.* She noted that only meds made his pain better. *Id.* She indicated that the pain affected the UC's sleep, mood, work (writing the word ''most''), daily activities, energy, and relationships, and that his quality of life off medications was worse (as opposed to better) and that his quality of life was worse ''off medications'' and was better ''on medications.'' *Id.* She noted that the UC's past medical and surgery record had not been received, and under ''social history,'' she circled ''none'' for no history of ''Etoh'' (alcohol use), ''smoke'' and ''drugs.'' *Id.* She also drew a single dash in the space for urine drug screen results, and indicated his past imaging studies included an MRI. *Id.*

On the second page, Respondent checked ''All negative'' for her review of the UC's systems. *Id.* at 26. As for the physical exam, Respondent either drew a circle or scribbled around various words to indicate that various portions of the purported exam were normal.[10] *Id.* Respondent also documented that she had performed a neurological exam which included testing the UC's cranial nerves, a sensory exam, a deep tendon reflex test of both the upper and lower extremities, and a muscle strength test of both his ''upper'' and ''lower,'' each of which she found to be normal. *Id.* Respondent also made various entries indicating that she had performed various orthopedic tests, including a straight leg raise on his right leg which provided a positive result, a Kemps test of the UC's lumbar region which was also positive, as well as several other tests, none of which are corroborated by the video. *Id.; see also* GE 5, V–0002, at 15:32:50–15:36:21 and V–0003, at 15:36:30–15:54. This page also includes four diagrams of the human body including a posterior view, which appears to have the letter ''T'' for ''Tenderness'' drawn over the lower back and buttocks. GE 11, at 26.

The form's third page includes Respondent's ''Assessment.'' *Id.* at 27. Therein, Respondent placed a check mark next on the line which states ''Patient not satisfied, request change,'' wherein she handwrote ''still ↑ pain on 4 q day—stuntman.'' *Id.* Respondent also placed a check mark on the line for ''Patient will take meds as prescribed and reports *no* side effect'' as well as the line for ''Patient will take meds as prescribed and reports these side effects.'' *Id.* Respondent also placed a checkmark next to the line for ''Activities of living quality are improved with medication.'' *Id.*

In the Diagnosis section, Respondent checked ''Anxiety,'' ''Disc Bulge,'' ''Muscle Spasms,'' ''Chronic Non-Malignant Pain Syndrome'' and ''Other,'' after which she handwrote what appears as ''post. Bulge c torn annulus + bilat foraminal encroachment.'' *Id.* And in the section for her ''Plan,'' she made a checkmark next to ''Referral: Ortho, Neuro, Psych, Sloan Center/Mr. Brown, CAP.'' *Id.* She also indicated a negative ''Tox screen'' and negative ''Chemistry screen''; however, neither test was done at this visit. *Id.* Finally, she placed check marks next to the entries for ''Wt loss, smoking cessation, reduce salt and caffeine'' and ''Goal to relieve 80% of pain, accomplished.'' *Id.*[11] *Id.*

As with the form used at the previous visit, page 3 lists both controlled and non-controlled medications with specific dosage quantities and quantities. As before, the only narcotic listed is Roxicodone 30 mg with four different quantities: 84, 112, 140 and 168. Consistent with the prescriptions she issued, Respondent checked ''Roxicodone 30 mg and circled ''#140,'' as well as Klonopin and circled both ''1 mg'' and ''#28.'' *Id.* She also checked Flexeril and Ibuprofen 400mg. *Id.*

The Expert's Review of Respondent's Prescribings to the UC

Dr. Hoch, the Government's Expert, reviewed the medical files, transcripts and recordings of the UC's two visits with Respondent. Based on his review, the Expert found that Respondent ''failed to establish a sufficient doctor/patient relationship with [UC] and that the prescribing of controlled substances was outside the usual course of professional practice and for other than a legitimate medical purpose.'' GE 24, at 3. The Expert provided extensive reasons for his conclusion.

First, the Expert explained that ''[t]he documented record fails to show that [Respondent] conducted an adequate evaluation of the [UC]'' in that ''a complete medical history was not taken.'' *Id.* According to the Expert, the records lack sufficient documentation ''to show that [Respondent] made a serious inquiry into the cause of [UC's] pain.'' *Id.* The Expert further explained that ''[i]n a valid doctor/patient relationship, a physician must inquire into whether the pain is the result of an injury or another disease process. That was not sufficiently done. All [Respondent] did was determine that [UC] was a stunt performer and had not been in a car accident.'' *Id.* at 3.

The Expert also found that while the UC ''stated that he had seen as many as six other doctors for his pain'' and ''signed a release authorizing [PB] to obtain and review his prior medical records,'' there are no records from physicians who treated the UC prior to his going to PBM. *Id.* According to the Expert, ''[i]n completing a sufficient medical history, it is important to review the records of other physicians who have treated the patient.'' *Id.*

The Expert further found that Respondent ''failed to conduct an adequate physical examination of'' the UC. *Id.* According to the Expert, during both physical exams, the UC ''failed to demonstrate pain sufficient to justify the repeated prescribing of controlled substances, especially strong opioid medications such as thirty milligram tablets of oxycodone.'' *Id.* The Expert specifically faulted Respondent for determining that the UC ''suffered from muscle spasms without any evidence,'' as well as for concluding that ''he suffered from anxiety without any inquiry into his mental state or sleeping habits,'' and when, ''[i]n fact, [he] never disclosed that he suffered from anxiety.'' *Id.* at 3–4. The Expert then observed that ''Respondent noted 'anxiety' in the medical record and issued prescriptions for clonazepam which specifically stated they were being issued to treat anxiety.'' *Id.*

The Expert also faulted Respondent for having increased the quantity of the UC's oxycodone prescription from 112 to 140 dosage units at the July 16, 2012 visit. *Id.* at 4. As the Expert found, Respondent ''increased the amount of oxycodone she prescribed without any medical justification, falsely writing that [UC's] pain had increased, when, in fact, [UC] initially rated his untreated pain as a '2' and changed the rating only after being prompted.'' *Id.*

[9] Respondent drew relatively straight lines in the spaces next to the words ''Surgery,'' ''PT,'' and ''Injections.'' GE 11, at 25.

[10] Specifically, for ''Heent,'' she circled ''inspection''; for ''Chest,'' she drew scribble around ''clear''; for ''Cor,'' she scribbled around ''rrr''; for ''Abd,'' she scribbled over ''soft''; for ''ext,'' she scribble over ''nontender''; and for ''Psych,'' she circled ''Ox3.''

[11] The plan section also included entries for ''[i]f any problems develop, go to ER for any emergency,'' ''[y]oga, stretching, swimming or other cardiovascular exercises suggested,'' ''[f]ish oil recommended at 3–6 grams per day/glucosamine and Chondroitin Sulfate recommended,'' and ''[d]iscussed informed consent, risks/benefits of given medications, alternative therapies; pt understands.'' GE 11, at 27. Next to each of these Respondent made stray marks, the intent of which cannot be determined.

Next, the Expert faulted Respondent because she ''also failed to determine and/or document the effect of pain on the [UC's] physical and psychological function.'' *Id.* The Expert further noted that ''[t]here is no documentation in the record to show that [Respondent] made any attempt to adequately address this important standard of pain management'' and that she ''appeared to coach [the UC] into stating that the pain affected his 'work' after he repeatedly states he was seeking narcotics to recover from muscle soreness due to exercising.'' *Id.*

The Expert also found that Respondent ''failed to create and/or document a sufficient treatment plan.'' *Id.* The Expert explained that despite UC's history of treatment at PBM and receipt of ''prescriptions for controlled substances on prior occasions, [Respondent] recommended no further diagnostic evaluations or other therapies.'' *Id.* The Expert then observed that the UC's ''MRI . . . failed to demonstrate serious enough pathology for him to receive the large amounts of controlled substances that were prescribed.'' *Id.* The Expert further explained that ''[b]ulging discs can usually be addressed by other means such as physical therapy, exercise, work strengthening programs, abdominal core training, anti-inflammatories, and at times, injections such as nerve blocks with corticosteroids,'' but that ''[n]one of these options was offered or discussed by'' Respondent. *Id.* The Expert then opined that ''[i]gnoring these options constitutes an inferior, if not non-existent, treatment plan.'' *Id.*

The Expert also concluded that his review of the transcripts and recordings of UC's visits with Respondent ''indicates that [Respondent] herself doubted there was a legitimate medical need to prescribe the large amounts of opioid medications that were prescribed.'' *Id.* The Expert specifically noted that ''[i]nitially, on May 31, 2012, [Respondent] stated that [the UC's] MRI showed 'nothing too terrible,'' adding that 'a bulge kind of doesn't mean anything' and that she would not 'give narcotics for spasms.' '' *Id.* (citing GE 7, at 4–5). The Expert also observed that ''[o]n the second visit, [Respondent] said she 'certainly wouldn't just give pain medicines and narcotics so [his] working out is better.' '' *Id.* (quoting GE 9, at 5).

The Expert further noted that Respondent ''never inquired as to the treatment UC may have received prior to coming to [PBM][,] [n]or did she discuss any non-narcotic treatment [he] may have received from any other doctor at PBM.'' *Id.* Based on his ''review of the medical records, transcripts and recordings'' of UC's two visits with Respondent, the Expert opined that: ''there was serious doubt as to whether treatment goals were being achieved. Yet there was no attempt by [Respondent] to evaluate the appropriateness of continued treatment except to increase the amount of narcotics and create a means by which [the UC] could fill his prescriptions without raising the legitimate concerns of pharmacists.'' *Id.* In the Expert's opinion, ''this shows there was an insufficient review of the course of treatment and the prescriptions provided by [Respondent] to [the UC were] inconsistent with [Respondent's] evaluation.'' *Id.* at 4–5.

Next, the Expert concluded that Respondent ''failed to sufficiently monitor [the UC's] compliance in medication usage.'' *Id.* at 5. The Expert noted that Respondent ''was well aware that [the UC] had run out of medication, and had illegally obtained both oxycodone and alprazolam from one or more friends.'' *Id.* The Expert noted that Respondent nonetheless ''increased the amount of oxycodone from 112 tablets to 140 tablets solely because of concerns that [the UC] might not return within 28 days, not because of any increase in pain.'' *Id.* (comparing GE 9, at 13 (discussing the two-week delay in appointment ''you need it two weeks ahead of time . . . alright let's go to one forty'') with GE 11, at 27 (medical record showing UC's pain increased despite taking four tablets a day)).

The Expert also found that Respondent ''ignored the numerous inconsistencies in the records which constitute red flags for abuse and/or diversion.'' *Id.* As support for this finding, the Expert noted that the medical record for July 16, 2012 indicates that the UC's pain affected his sleep, mood, work, daily activities, energy, and relationships, yet during the actual consultation, UC initially said the pain affected only his ''recovery time from working out.'' *Id.* However, when Respondent told the UC that this would not justify prescribing narcotics, the UC changed his answer to ''work'' and provided this answer in response to the questions of whether the pain affected his sleep and relationships. *Id.* (citing GE 11, at 5–6).

The Expert also noted that at the July 16, 2012 visit, the UC initially stated that his pain ''level was 'two' without medication,'' but when prompted by Respondent, he ''changed it to 'four or five.' '' *Id.* (citing GE 9, at 4–5). Moreover, the Expert noted that ''the medical record for that date shows a pain level of 1–2 [on the patient follow-up sheet], and a pain level of 5'' on the form signed by Respondent. *Id.* (citing GE 11, at 29 and 25). The Expert also noted that the form signed by Respondent documents that the UC's pain [was] made worse by ''sitting, standing in one position too long,'' but there is nothing on the record to indicate that he made such a claim. *Id.* (citing GE 11, at 29). The Expert thus opined that, at a minimum, Respondent ''should have had a discussion with [the UC] about his need for more medication, and made specific inquiries to determine if and how [his] pain had increased,'' given that the UC ''demonstrated that he was at risk for misusing his medications.'' *Id.*

Next, the Government's Expert opined that ''there was no legitimate medical justification for the amount of oxycodone prescribed to'' the UC by Respondent. *Id.* As support for his opinion, the Expert noted that ''prior to his first visit with [Respondent], [the UC] had not been seen by a [PBM] physician since January 18, 2012,'' and therefore, ''he was, in all likelihood, opiate naïve on May 31, 2012.'' *Id.* The Expert then explained that ''[p]rescribing 112 thirty milligram tablets of oxycodone in this situation was without medical justification and dangerous.'' *Id.*

The Expert also found that ''there was no justification for increasing the amount [on] July 16, 2012.'' *Id.* As Expert explained, although the UC ''indicated he ran out of medication because he was two weeks late for his second appointment with [Respondent], there was no indication that he would be late again. Also, there was no notation in the file to prevent UC from returning in 28 days and receiving another prescription identical to the one received on July 16, 2012.'' *Id.* The Expert thus found that Respondent ''failed to inquire into, or otherwise determine, whether there was a legitimate medical need for the additional medication.'' *Id.* She also ''failed to adjust the quantity and frequency of the dose of oxycodone according to the intensity and duration of the pain and failed to justify the additional prescription on clear documentation of unrelieved pain.'' *Id.*

The Expert further opined that ''there was no legitimate medical justification for prescribing clonazepam, a benzodiazepine utilized to treat anxiety and, in some cases, sleep disorders.'' *Id.* The Expert specifically found that Respondent ''made no attempt to a[ss]ess [the UC's] mental state or his sleeping habits.'' *Id.* at 5–6. The Expert noted that during the UC's first visit with Respondent, he ''provided no

information about these conditions except to say he 'used to take a little bit of Xanax to sleep, but [that he could] probably work without it.' '' *Id.* at 6. The Expert also observed that when the UC was asked during his second visit if ''his pain affected his sleep, [he] said 'work.' '' *Id.* (citing GE 9, at 5). The Expert thus found that ''[t]he record is devoid of any medical evidence justifying the need for prescribing clonazepam.'' *Id.* The Expert also noted that because Respondent ''fail[ed] to retrieve or cancel'' the clonazepam prescription that she had given the UC at the May 31, 2012 visit, she enabled the UC ''to obtain twice the amount as directed . . . by providing a second prescription [to him] on July 16, 2012.'' *Id.*

The Expert's ultimate conclusion was that the controlled substance prescriptions Respondent provided to the UC ''were not justified given [the UC's] complaints and medical findings, and certainly not in the dosages or frequencies prescribed.'' *Id.* at 6. The Expert further opined that the controlled substance prescriptions Respondent issued to the UC ''lacked a legitimate medical purpose and were issued outside the usual course of professional practice.'' *Id.* at 15.

The Expert's Review of Other Patient Charts

D.G.

On November 2, 2010, D.G., who was then 32 years old and listed his residence as being in Niceville, Florida, which is nearly 600 miles from Pompano Beach, first went to PBM and was seen by Dr. Gabriel Sanchez. GE 17, at 5, 22. According to the intake forms, D.G.'s chief complaint was ''sharp, intermittent pain in neck & upper back'' which started in 1999. *Id.* at 5. D.G. reported that on ''a scale of 0–10,'' with ''0 being no pain and 10 being the worst possible pain,'' his pain with medication was ''4'' and his pain without medication was ''9,'' and that the ''inciting event[s] [were a] weightlifting accident, several car accidents.'' *Id.* at 5. He further reported that he had chiropractic procedures, and that he tried anti-inflammatories and anti-depressants, as well as oxycodone, Xanax, Vicodin and Percocet. *Id.* D.G. also noted that he had seen other doctors for his pain and that he thought he may have ''depression.'' *Id.* On another form, he checked that his symptoms ''in the past year'' included migraine headaches, loss of sleep, and neck and shoulder pain. *Id.* at 6.

D.G. also signed a Pain Management Agreement in which he agreed that the ''controlled substance prescribed must be from the physician whose signature appears on this agreement or in his/her absence, by the covering physician, unless specific authorization is obtained for an exception.'' *Id.* at 11. He also agreed that he would ''not attempt to obtain controlled medications, including opiate pain medications, controlled stimulants, or anxiety medication from any other doctor.'' *Id.* D.G. also signed two releases for the release of the information by which he authorized PBM to obtain a prescription profile from a pharmacy and diagnostic reports from a diagnostic center.[12] *Id.* at 18, 20. However, while D.G. indicated on the intake forms that he had seen other doctors for his pain, as well as that he had previously used anti-depressants, his file does not contain a release for a physician's treatment records. *See generally id.* Moreover, while it appears that PBM obtained D.G.'s MRI report on the date of his first visit, it did not obtain his prescription profile until July 6, 2011. *See id.* at 120–22.

D.G. was also subjected to a drug test at his first visit. *Id.* at 131. The test results were negative for all drugs. *Id.*

At D.G.'s first visit, Dr. Gabriel Sanchez[13] documented his findings on a one-page form including a diagnosis of chronic discogenic neck pain and issued him prescriptions for 150 Oxycodone 30 mg, 60 Oxycodone 15 mg, 60 Xanax 2 mg, 30 Motrin 800, and 30 Nortriptyline 25 mg. *Id.* at 128–30. One month later on December 2, 2010, D.G. returned to PBM, where Dr. Sanchez reissued each of the prescriptions. *Id.* at 124–26.

Thereafter, D.G. did not return to PBM until July 6, 2011. *Id.* at 117. While D.G. completed a Follow-Up Sheet on which he noted that his pain was ''always there,'' that it got ''worse when [he] move[d] in certain ways,'' that it affected multiple life activities and provided pain ratings both with and without medication, the two-page visit note is largely blank and contains no entries in the section of the form for documenting his prescriptions. *Id.* at 117–19. Nor does D.G.'s file contain copies of any prescriptions bearing the date of July 6, 2011. *See generally id.*

D.G.'s record shows that his next visit occurred on September 7, 2011, on which date he again noted on the Follow-Up sheet that his pain was ''always there,'' that it got ''worse when [he] moved in certain ways,'' checked various activities his ''pain affects,'' and rated his pain ''without medication'' as an 8, and ''with medication'' as between 3 and 4. *Id.* at 113. At the visit, D.G. was required to complete a form titled as ''MEDICAL DISCLOSURE (LAST 30 DAYS).'' *Id.* at 115. On the form, D.G. wrote ''N/A'' in both the space where he was to list ''Prescriptions [sic] meds from other physicians'' and ''Prescriptions [sic] medications from other source.'' *Id.*

Yet a Drug Screen Results Form indicates that D.G. tested positive for oxycodone at this visit. *Id.* at 116. Moreover, a form titled as ''Patient Compliance Instructions,'' which was signed by D.G. at this visit, states: ''All Patients Must Pass Their Initial and Random Urine Drug Screening Test!'' *Id.* at 114. However, notwithstanding the inconsistency between what D.G. reported on the Medical Disclosure Form and his positive oxycodone test, Dr. T.R. issued D.G. prescriptions for 140 Oxycodone 30, 25 Xanax 2 mg, 50 Mobic 7.5 mg, and 28 Nortriptyline 50 mg. *Id.* at 110–111.

Thereafter, D.G. went to PBM monthly where he saw Dr. T.R., who increased his oxycodone 30 prescription from 140 to 168 du (during his November 2, 2011 visit ''as per pt. request'') as well as 24 Xanax 2 mg, (along with Nortriptyline and Mobic), after which D.G. saw Dr. A.E., who also issued him prescriptions 168 du of oxycodone 30 and 24 Xanax 2 through March 22, 2012. *Id.* at 74–110.

On April 19, 2012, D.G. was treated by Respondent. On his ''Patients [sic] Follow-Up Sheet,'' he again reported that his pain was always there, that it was worse when he moved in certain ways, and that it affected his social activities, work, exercise, mobility and sleep. *Id.* at 61. He rated his pain ''with medication'' as a 3 and ''without medication'' as an 8. *Id.* He also indicated that he was satisfied with his current medication and would not like to change it. *Id.*

In the ''Pain History Follow Up'' section of the visit note, Respondent indicated that D.G. has severe neck pain which was throbbing, sharp, and tingling, that the pain's ''duration'' was 15 years, and wrote ''football'' as the precipitating event.[14] *Id.* at 65. She

[12] D.G.'s patient file includes an MRI report dated April 10, 2010 which showed degenerative changes at C5–6 and C6–7, mild kyphosis at C5–6, a bulging disc at C4–5 with no spinal stenosis, narrowing of the disc at C5–6 and C6–7 with herniated disc protrusions and mild bone spurs. GE 17, at 132–133. D.G.'s file also includes a patient profile from Santa Rosa Pharmacy covering the period of January 1, 2011 through July 6, 2011. *Id.* at 120–22.

[13] Dr. Sanchez's DEA registration was the subject of Show Cause proceedings and revoked effective October 25, 2013. *See Gabriel Sanchez,* 78 FR 59060 (2013).

[14] Respondent also drew a horizontal line (rather than a check mark) in the space for noting if the pain radiated. GE 17, at 65. It is unclear what this line was intended to document, if anything.

checked ''insomnia'' under co-morbidities, and noted that his pain level was 8 when ''off meds'' and 3 when ''on meds.'' *Id.* Under ''New Events Since Last Visit'' she wrote ''none—some ↑ pain at work.'' *Id.*

Under Review of Systems, she indicated that all were negative. *Id.* Under PE [Physical Exam], she made checkmarks suggesting that she had examined D.G.'s HEENT, Chest, Cor, Abd, and made scribbles next to Skin, Ext, Neuro/psych and Gait. *Id.* She added handwritten notes regarding the extent to which he could rotate his neck as well his range of motion for the extension and flexion of his neck, a notation ''Hand grip'' followed by an illegible word, and noted ''Lock Box discussed.'' *Id.*

On the second page of the note, Respondent placed check marks next to ''yes'' for various neurological exam items and made no notation that D.G. had any focal deficits. *Id.* at 64. In the orthopedic section, she indicated that she had done a straight leg raise test on both D.G.'s right and left legs with a negative result on each leg. *Id.*

In the section for her ''Assessment,'' Respondent placed a checkmark next to ''Patient satisfied, doing well on current medication and treatment plan; pain condition stable.'' *Id.* She also placed a checkmark next to ''Patient taking meds as prescribed and no adverse side effects, no new problems and no new changes.'' And as for her ''Diagnosis,'' Respondent checked ''Cervicalgia,'' ''Disc Herniation C56/67,'' ''Hypertension'' and ''Chronic Non-Malignant Pain Syndrome.'' *Id.*

Under Plan, Respondent marked a series of marks next to each item on the list, to include ''wt. loss, smoking cessation, reduce salt and caffeine, F/U with PCP''; ''Refer to PT, neurologist, neurosurgeon, orthopedist, psychiatrist, addiction specialist as needed''; ''urine tox screen twice a year or as needed to monitor addiction/diversion''; ''Yoga, stretching exercises, Fish oil at 3–6 grams/day; Glucosamine/Chondroitin Sulfate as suggested''; ''Discussed informed consent, risks/benefits of given medications, alternate therapies; pt understands''; and ''Continue meds, patient understands importance of weaning meds to minimum effective dose.'' *Id.*

As with the UC's visit notes, Page 3 contained a list of medications at varying strengths and dosages, but only listed a single narcotic, that being Roxicodone 30 mg, next to which Respondent wrote a checkmark and circled ''#168'' (the maximum number listed). *Id.* at 63. She also placed a checkmark next to Xanax, circling ''2 mg'' and handwrote ''↓'' and ''#20'' (fewer than the listed choices of #28 or #56). *Id.* In addition, she placed a checkmark next to Amitriptyline, after which she wrote ''50'' and circled ''#28'' and wrote in Lisinopril under ''Other Meds.'' *Id.* Under Radiology, she wrote ''MRI Cervical,'' and under Consults she wrote: ''MS Contin 30 BID #56.'' *Id.* On the form she also added: ''Goal: Cont. working ↑ meds so He can cont his business.'' *Id.* She also wrote ''Labs next time'' and signed and dated the form. *Id.*

A computer-generated ''Encounter Summary'' lists diagnoses of ''Cervical Spinal Stenosis,'' ''Cervicalgia,'' and ''Chronic Pain Syndrome.'' *Id.* at 66. Under medications, it lists each of the drugs discussed above including 56 MS Contin 30 mg. *Id.* The Encounter Summary also lists a prescription for an ''mri no contrast C Spine DX: herniated disc.'' *Id.*

On May 17, 2012, D.G. returned to PBM and again saw Respondent. D.G. filled out his ''Patients [sic] Follow-Up Sheet'' answering each question exactly as before, including indicating his pain was a ''3'' with medication and an ''8'' without medication. *Id.* at 58.

Respondent filled out the Pain History Follow Up sheet, indicating that the neck was the location of D.G.'s pain, that it was severe, throbbing, and sharp, that it had been present for 15 years and precipitated by ''football.'' *Id.* at 55. She listed no new events since D.G.'s last visit. Also, she checked no co-morbidities and circled ''N'' for ''Psych visits/SS Disability.'' *Id.*

Under ROS, she noted that all findings were negative, and in the PE section, she made a series of scribbles over the various descriptors for normal findings for each exam item. *Id.* On the body diagram's posterior view, she circled the neck portion and wrote ''Rotation 80 R 90 L'' as well as ''Flex 45 Ext 10''; she also circled both elbows and noted ''Reflex +2='', and finally, she circled both hands and wrote ''no hand numbness good grip.'' *Id.*

In the neurological exam section, she checked ''Yes'' next to each of the items listed, and in the orthopedic section, she again noted a negative for both a right and left leg raise test. *Id.* at 56. In the Assessment section, she placed a check mark next to ''Patient satisfied, doing well on current medication and treatment plan; pain condition stable'' and ''Activities of living, quality of life improved with medication.'' *Id.*[15]

Under Diagnosis, she again checked Cervicalgia, Disc Herniation ''C56/67,'' Hypertension and Chronic Non-Malignant Pain Syndrome. *Id.* However, in contrast to D.G.'s previous visit, she also placed check marks next to ''Anxiety'' and Insomnia.'' *Id.* Under Plan, she checked each item as at the previous visit, but circled ''F/U with PCP'' and noted ''HTN.'' *Id.* And below the Plan section, she handwrote ''*goal:* cont to be sales rep.'' *Id.*

On the page containing the list of medications, strengths and dosages, Respondent again checked the boxes for Roxicodone 30 (circling ''#168''), Xanax 2 mg (writing ''↓'' and ''#15''), and Amitriptyline #28, writing ''50'' for the drug strength. *Id.* at 57. She noted ''must get PCP to get BP evaluation [and] meds,'' ''MRI C-Cervical'' and ''MS Contin 30 BID #56,'' and added notes about Lisinopril. *Id.* She also wrote ''next mth. stop Xanax'' and ''Add Klonopin 1 mg BID #56'' at the bottom of the page below her signature and the date. *Id.* The Encounter Summary printout reflects the prescriptions listed. *Id.* at 54.

D.G.'s next appointment with Respondent was on June 14, 2012. *Id.* at 47. He reported no changes on the ''Patients [sic] Follow-Up Sheet,'' indicated that his pain level was 3 ''with medication'' and ''8'' ''without medication,'' and that he was satisfied with his current medication. *Id.* at 51.

Respondent filled out the revised Pain History form, with few differences from the previous visit, notably that D.G.'s ''Pain Scale off meds (0–10) [was] 10''; ''Pain Scale on meds (0–10) [was] 3.'' *Id.*at 47. She checked ''insomnia'' as a co-morbidity, and for the question ''[w]hat makes your pain better,'' she left blank ''lying, resting, stretching, exercise, heat, ice massage'' and checked ''other'' with ''meds'' handwritten next to it. *Id.* She also made a handwritten notation ''Has Lock Box!'' *Id.* On the line for what activities the pain affected, she place a checkmark next to sleep, a horizontal line next to mood, and short diagonal line next to work, energy, and relationships. *Id.* She also indicated that D.G.'s quality of life was worse ''off medications'' and better ''on medications.'' *Id.* Under ''Past Imaging/Studies,'' she circled ''MRI'' and noted ''4–10 see DX section.'' *Id.*

As at the previous visit, she checked ''all negative'' in the review of system, scribbled over various normal findings in the physical exam section, circled ''yes'' for each item in the neurological section, and indicated that various ''orthopedic'' tests were negative. *Id.* at 48. *S*he also noted that D.G.'s cervical range of motion was 45 degrees in flexion and 10 degrees in extension, and made findings as to D.G.'s ability to rotate his neck. *Id.*

[15] Respondent made no mark next to ''Patient taking meds as prescribed. . . .'' GE 17, at 56.

Under Assessment, Respondent checked the line for ''Patient Satisfied, understands how to take current medication and treatment plan.'' *Id* at 49. In the Diagnosis section, Respondent checked ''Anxiety,'' ''Cervicalgia,'' ''Disc Herniation,'' ''Hypertension,'' ''Insomnia,'' and ''Chronic Non-Malig Pain Syndrome.'' *Id.*

As for her plan, Respondent checked the line for ''PCP obtained/referred for following conditions'' after which she added: ''For HTN in Ft Walton Bch, Fl,'' below which she wrote: ''Pt will Bring copy of Doctors HTN Report Next Visit.'' *Id.* She also noted: ''Tox screen due 2 mths'' and ''Chemistry screen due now—pt will get,'' as well as checked several other line items. *Id.*

Respondent prescribed 168 Roxicodone 30 mg, 56 MS Contin 30 mg BID, discontinued the Xanax and added #56 Klonopin 1 mg.[16] *Id.* at 49; *see also id.* at 45–46 (copies of Rxs and Encounter Summary). On a form with the caption: ''Reason for Prescribing Over a 72 hour Quantity of Substance(s),'' Respondent made additional notations, including: ''CMP script—pt will do outside lab,'' ''UDS next 1–2 mth,'' ''C-Spine MRI with script given previously,'' ''Must see PCP for HTN Pt advised he must 1. Get labs 2. Bring copy of physician report on HTN or can *not* be seen next time.'' *Id.* at 50.

D.G.'s file contains a memo from the Clinic Director of the Hope Medical Clinic, a free clinic located in Destin, Florida, which was faxed to PBM on July 11, 2012, one day before D.G.'s next appointment. *Id.* at 42. The memo stated that D.G. ''has an appointment with us on September 20th where we will be able to begin his long term primary care for chronic illness. Our program is full until this date as our services are at no cost to patients.'' *Id.*

On July 12, 2012, D.G. returned to PBM and again saw Respondent. On the ''Patients [sic] Follow-Up Sheet,'' he again indicated that the pain was ''always there,'' that it affected his social activities, work, exercise, mobility, and sleep, that the pain was 3 ''with medication'' and 8 ''without medication,'' and that he was satisfied with his current medication. *Id.* at 40.

Respondent filled in the blanks in the Pain History section of the visit note, making the same notations as before, including that D.G.'s pain scale ''off meds'' was ''10'', but ''3'' with medication. *Id.* at 35. She again noted that a cervical MRI from ''4–10'' was the only imaging report. *Id.* Her examination notations on the remaining forms were nearly identical to those made at the previous visit. *See id.* at 37–38. Moreover, she checked the same diagnosis findings and the same items under her plan. *Id.* Respondent again prescribed 168 Roxicodone 30 mg, 56 Klonopin 1 mg, 56 MS Contin 30 mg BID, and Amitriptyline. *Id.* at 38; *see also id.* at 33, 36 (copies of prescriptions and Encounter Summary).

The Expert reviewed D.G.'s medical file, and concluded that the controlled substance prescriptions Respondent issued to D.G. between April 19, 2012 and July 12, 2012 were issued outside the usual course of professional practice. GE 24, at 13. The Expert set forth multiple reasons for his conclusion.[17]

First, he found that ''the medical history and physical examinations [were] inadequate and that it was not reasonable for Registrant to rely on the evaluations of other providers at'' PBM. *Id.* He further found that Respondent ''failed to conduct an adequate physical examination or take a satisfactory medical history of D.G.'' in that ''she relied on . . . superficial checklists which are insufficient for evaluating the types of complaints that D.G. communicated.'' *Id.*

The Expert also found that Respondent ''prescribed additional narcotics without any medical justification.'' *Id.* The Expert specifically noted that ''on April 19, 2012, she added a prescription for morphine sulfate, stating that . . . D.G. needed more medication in order to continue his restaurant business and that his pain had increased at work.'' *Id.* The Expert noted that that ''[t]his contradicts statements D.G. made that same day, in which he declared he was satisfied with his current medication.'' *Id.*

The Expert further found that D.G.'s ''records contain no evidence that [Respondent] addressed the effect of pain on D.G.'s physical and psychological function. The Expert further explained that ''the checklist is devoid of any explanation for how D.G.'s pain affected his social activities, mobility, work, exercise or sleep.'' *Id.* (citing GE 23, at 39–42, 49–52, 57–60, 62–63, 65–67).

The Expert similarly opined that Respondent's ''treatment plan was wholly inadequate and . . . consisted only of a checklist of recommendations.'' *Id.* The Expert noted that there is no evidence that any of the recommendations were either discussed or followed. *Id.* He also noted that while Respondent placed a checkmark suggesting that referrals to physical therapy and other specialist physicians were part of her plan for D.G., there is no evidence ''that any referrals were made.'' *Id.* at 13–14.

Finally, the Expert opined that Respondent ''ignored numerous 'red flags' for diversion.'' *Id.* at 14. More specifically, the Expert noted that while D.G. had signed PBM's pain management agreement, in which he agreed that he would not obtain controlled substances from any other doctor, the Santa Rosa Pharmacy printout showed that he had obtained both oxycodone and alprazolam in June 2011. GE 24, at 14. Indeed, the printout showed that he had obtained controlled substances from another physician, who was located in Lake Clark Shores (which is in Palm Beach County), on multiple occasions between his visit in December 2010 and July 2011. GE 17, at 122.

The Expert noted that on September 7, 2011, D.G. ''tested positive for oxycodone despite no evidence he had received a prescription after June 2011.'' GE 24, at 14. He also noted that ''[o]n that date, [D.G.] denied having seen other 'medicating prescribing pain doctors' and denied receiving any prescriptions from other physicians.'' *Id.*

Finally, the Expert noted that D.G. resided in Niceville, Florida, which is approximately 596 miles from PBM. *Id.* The Expert observed that ''there was no information in the medical records to explain why D.G. would travel such an extraordinarily long distance'' to receive medical care. *Id.* He then concluded that ''[t]hese red flags indicate . . . that Respondent failed to monitor D.G.'s compliance in medication usage and failed to give special attention to D.G., who was clearly at risk for misusing his medications and posed a risk for medication misuse and/or diversion.'' *Id.* The Expert thus concluded that the controlled substance prescriptions Respondent issued to D.G. ''lacked a legitimate medical purpose and were issued outside of the usual course of professional practice.'' *Id.* at 15.

Patient J.A.

On February 28, 2011, J.A., a resident of Plantation, Florida, was initially treated at PBM by Dr. Gabriel Sanchez. GE 18, at 132–33. At his first visit, his chief complaint was nerve damage to his back and neck which had started

[16] She also prescribed 28 Amitriptyline 50 mg.

[17] Earlier in his declaration, the Expert explained with respect to the individuals whose charts he reviewed, that Respondent ''provided them with prescriptions for controlled substances in contravention of the standards of care and practice in the State of Florida and with indifference to various indicators or 'red flags' that the patients were engaged in drug abuse and/or diversion.'' GE 24, at 6.

five years earlier. *Id.* at 4. J.A. wrote that the inciting event was ''burn + hit with pot in back,'' and that his pain was an 8 ''with medication'' and a 10 ''without medication.'' *Id.* He also reported he had had chiropractic procedures and trigger point injections, that he had tried anti-inflammatories and Gabapentin, as well as oxycodone, methadone, Xanax and Vicodin. *Id.* He also indicated that he had seen other doctors for his pain. *Id.*

J.A. also signed two releases for medical records. *Id.* at 19–20. However, while an MRI was faxed to PBM, and that MRI report even lists the name of the referring physician, J.A.'s file contains no records from that physician or any other physician who treated him. *Id.* at 135; see *generally* GE 18.

J.A. presented an MRI report for his lumbar spine (which was done two months earlier) which showed ''[m]inimal central bulges L4–5 and L5–S1 without nerve root compressions'' and ''[m]inimal facet and ligamentum flavum hypertrophy at the same 2 levels.'' *Id.* at 135. He was also subjected to a urine drug test. *Id.* at 134.

According to the initial evaluation form, during the neurological exam, J.A. had a positive Spurlings test bilaterally and a positive straight leg raise test bilaterally. *Id.* at 133. Dr. Sanchez also documented range of motion findings for both J.A.'s cervical and lumbar spine, as well as that J.A. had chronic mid-back and neck pain for 8 years and that his MRI showed disc bulges at L4–S1. *Id.* The only other exam findings were that J.A.'s lungs were ''clear'' and his extremities were ''N.'' *Id.*

Dr. Sanchez listed his diagnosis as ''Chronic Discogenic Mid Back and Neck Pain.'' *Id.* He prescribed to J.A.: 150 Oxycodone 30 mg, 60 Methadone 10 mg, 60 Xanax 2 mg, as well as 30 Ibuprofen 800 mg, and 30 Nortryptyline 25 mg. *Id.* at 131–33. Other notations on the evaluation note state: ''Recommend Orthopedic evaluation,'' ''Needs blood work'' and ''Needs MRI Thoracic.'' *Id.* at 133.

J.A. was seen monthly at PBM by Dr. Sanchez and other physicians through July 2011, and again on October 24, 2011. *Id.* at 98–130. At his March 29, 2011 visit, J.A. reported that his pain relief was an ''8–10/10'' and Dr. Sanchez reissued the same set of prescriptions. *Id.* at 125–27. At his April 25, 2011 visit, J.A. reported that his pain with medication was a 4; Sanchez again issued the same set of prescriptions. *Id.* at 121–22.

Yet at his May 26, 2011 visit, J.A. reported that his pain level was a 10 ''with medication'' and either 6 or 8 ''without medication.'' [18] A different doctor saw J.A., noting that he was at the clinic for a follow up of chronic ''lower back'' pain but also noting under his Physical Exam findings that J.A. was ''in no acute distress.'' *Id.* at 113. While this physician prescribed 150 oxycodone 30, he also reduced the quantity of J.A.'s methadone prescription to 28 dosage units and his Xanax prescription to 28 one (1) mg. dosage units. *Id.*

On June 23, 2011, J.A. was seen by still another doctor, who noted that he complained of ''constant pain upper thoracic spine'' and that his pain level was ''9/10.'' *Id.* at 109. The doctor noted that J.A. had said that he had gone for an MRI of the thoracic spine but that the MRI was not in the chart. *Id.* As for his PE findings, the doctor noted: ''neck limited motion []flexion'' and ''[t]enderness over most of [t]horacic [s]pine.'' *Id.* The doctor issued J.A. prescriptions for 140 oxycodone 30 mg and 28 Xanax 1 mg, while discontinuing the methadone. *Id.* at 107–09.

J.A. returned to PBM on July 21, 2011, this time listing his pain as an 8 ''with medication'' and a ''10'' without medication. *Id.* at 103. The examining physician documented that J.A.'s pain radiated ''down the back'' and was ''constant [and] aching.'' He also drew diagonal lines next to ''Physical Therapy'' and ''Chiro.'' *Id.* at 103. As for his ''Pertinent Physical Findings,'' he listed ''L/S F30 E10,'' ''Rotational ROM Fair,'' ''Head/Toe—wnl''; it also appears that he documented a positive finding on the ''SLR,'' although a portion of the entry is illegible. *Id.* at 104. The physician listed his diagnoses as ''chronic Discogenic LBP'' and ''Lumber Facet Syndrome.'' *Id.* The physician issued J.A. a prescription for 160 oxycodone 30. *Id.* He also resumed prescribing methadone 10 (28 dosage units) and doubled the strength of the Xanax prescription to 2 mg dosage units. *Id.*

J.A. did not return to PBM until October 24, 2011, three months later, when he was seen by Dr. T.R. *Id.* at 95. On the ''Patients [sic] Follow Up Sheet,'' J.A. indicated that his pain was 6 ''with medication'' and 10 ''without medication.'' *Id.* at 100. However, he did not indicate that the pain affected any life activities. *Id.* He was also subjected to a drug test, which was positive for opiates/morphine, methadone and oxycodone, *id.* at 43, even though he had not been at the clinic in three months and denied seeing other pain physicians who prescribed medication. *Id.* at 98.

Dr. T.R. noted his ''pertinent physical exam'' findings as ''H/T N,'' ''SLR—thigh pain,'' and the ''L/S ROM'' was ''F 60'' and ''E 20.'' *Id.* at 99. He listed his first diagnosis as ''Chronic Multifactorial LBP'' and listed the factors as ''Discogenic'' and ''Lumber Facet Syndrome''; he listed his second diagnosis as Insomnia. *Id.* Dr. T.R. issued J.A. prescriptions for 154 du of oxycodone 30 and 24 du of Xanax 2 mg, as well as Gabapentin and Mobic (meloxicam). *Id., see also id.* at 95.

On November 21, 2011, J.A. returned to PBM and saw Respondent for the first time. *Id.* at 93. A ''Patients [sic] Follow-Up Sheet'' in the record appears to have been completed by J.A. for that visit; it is, however, dated ''5/17/63'', which, according to the copy of J.A.'s Florida Identification Card in his patient file, is his date of birth. *Id.* at 96, *see also id.* at 22, 23. J.A. circled the upper back/thoracic spine as the area where he felt pain, but did not answer the questions: ''Is the pain always there?'' and ''Does the pain get worse when you move in certain ways?'' *Id.* at 96. He further indicated that his pain level was a 7 ''with medication'' and 10 ''without medication'' but left unanswered the remaining question whether ''the pain affected [sic] any of the following: Social Activities, Work, Exercise, Mobility, Appetite and Sleep.'' *Id.* at 96. J.A. also signed a Patient Compliance Instruction form regarding drug testing, proper use of medication, prohibitions against self-medicating, and zero tolerance for doctor shopping, trafficking, selling and distributing medications. *Id.* at 97.

Respondent completed a ''Pain History Follow Up'' where she indicated that the location of J.A.'s pain was his lower back. *Id.* at 93. She also circled the word ''radiation'' but then wrote ''none''; she also placed checkmarks indicating that his pain was severe and throbbing, and sharp, and that he had experienced the pain since 2001 when he suffered an accident noted as ''burn, chef-pot hit him.'' *Id.* Under ''Co-morbidities,'' Respondent checked ''anxiety'' and ''insomnia.'' *Id.* She noted that J.A.'s ''Pain Scale off meds (0–10)'' was ''9–10'' and that his ''Pain Scale on meds (0–10)'' was ''5–6.'' *Id.*

A handwritten note ''10–24 UDS + opi + mtd + oxy'' also appears on this form. *Id.* Under ''ROS,'' Respondent checked ''all negative unless checked,'' and for the various items listed under ''PE,'' she placed checkmarks or scribbled on the line next to normal findings. *Id.*

On the view of body diagram, Respondent circled the back of the neck

[18] As to the different ratings, on the numeric pain scale J.A. circled ''8'' and on the ''Faces Pain Rating Scale'' he circled ''6.'' GE 18, at 114.

and noted ''full ROM''; she also circled the entire back and wrote ''no obvious scars or defects,'' as well as the lower back, writing ''ROM WNL.'' *Id.* She also circled the back of the knees, but made no note, and off to the side of the diagram, she wrote: ''Risks discussed Sills.'' *Id.*

In the Neurological section, she filled in the ''Yes'' line for all neurological exam items indicating that there were no focal deficits, and in the Orthopedic Section, she indicated that she did a straight leg raise test which was negative for both legs. *Id.* And at the bottom of the form, she wrote ''old records show 10 yr ago 1° burn face & neck 2° back.'' *Id.* J.A.'s patient file includes records from the Emergency Department of the SUNY Stony Brook University Hospital from May 2001 corroborating that he was treated for burns in the upper back and posterior neck region. *Id.* at 90–92. Those records show, however, that J.A. was treated and discharged within three hours. *Id.* at 88, 92.

On the second page of the form for this visit, Respondent handwrote ''no'' next to the statement: ''Patient satisfied, doing well on current medication and treatment plan; pain condition stable.'' *Id.* at 94. She then put a checkmark next to each additional Assessment line entry, including ''Patient taking meds as prescribed . . . no adverse side effects, no new problems and no changes,'' ''Activities of living, quality of life improved with medication,'' as well as those regarding the denial of drug charges or arrests, medication storage and safety issues including lock box usage, and that the ''diagnosis and treatment plan are justified and based on diagnostic results, history and physical exam.'' *Id.*

Under the Diagnosis section, Respondent checked ''Disc Bulge'' and handwrote ''L45/L5S1,'' as well as checked ''Insomnia,'' ''Chronic Non-Malignant Pain Syndrome'' and handwrote ''Ligamentum flavum,'' ''Neuropathic pain?'' and ''Facet Hypertrophy.'' *Id.* She checked off all ''discussion points'' under the Plan, and circled ''neurologist'' on the line stating: ''refer to PT, neurologist, neurosurgeon, psychiatrist, addiction specialist as needed.'' *Id.* She also handwrote ''Labs next visit'' and ''work—[?] w/o pain.'' *Id.*

In the section for listing medications and other recommendations, she checked ''Roxicodone 30 mg,'' circled ''#140'' and handwrote ''wean next visit''; she also checked ''Xanax'' and circled ''1 mg'' and ''#28'' and handwrote ''wean ↓.'' *Id.* She checked ''Gabapentin,'' circled ''300 mg,'' handwrote ''BID'' and circled ''#168,'' and under other meds, she added ''Mobic 7.5 qd.'' *Id.* Finally, under ''Radiology,'' she wrote ''MRI c-spine'' and under ''Consults,'' she wrote ''neurology.'' *Id.* The Encounter Summary for this visit reflects that Respondent wrote J.A. prescriptions for 140 Roxicodone 30 mg ''for pain,'' 28 Xanax 1 mg ''for anxiety,'' as well as for 168 Gabapentin 300 mg and 28 Mobic 7.5 mg. *Id.* at 89.

Respondent next saw J.A. on December 19, 2011. *Id.* at 86. On the ''Patients [sic] Follow-Up Sheet,'' J.A. circled his upper back and thoracic spine, answered ''yes'' to the questions: ''[i]s the pain always there?'' and ''[d]oes the pain get worse when you move in certain ways?'' *Id.* J.A. did not, however, circle any life activities that his ''pain affected.'' *Id.* J.A. rated his pain as a 6 ''with medication'' and a 10 ''without medication.'' *Id.*

Respondent filled out the Pain History Follow Up form indicating that J.A. complained of severe lower back pain with no radiation due to burns from the 2001 incident. *Id.* at 84. She also indicated that J.A.'s pain was ''throbbing'' and ''sharp'' and checked ''insomnia'' as a co-morbidity. *Id.* She indicated that J.A. had not seen another pain management doctor in the past 28 days, that his quality of life was worse ''Off medications'' and better ''On medications,'' and that he had been ''working more hours'' since his last visit. *Id.* at 84. Moreover, she noted that his pain scale ''off meds'' was ''9–10'' and ''on meds'' was 7–8. *Id.*

In the ROS (Review of Systems) section, Respondent checked the line indicating ''all negative,'' and in the ''PE'' section, she checked the box for normal findings for every item except ''Ext,'' which she left blank. *Id.* On the posterior view of the body, Respondent circled the neck (next to which she wrote ''Rom'' followed by undecipherable scribble), the lower back (next to which she wrote ''Ext 10 Flex 90'') and knees (next to which she wrote ''Reflexes' followed by more scribble); off to the side of the diagram she wrote ''Risks discussed.'' *Id.* Finally, Respondent checked ''yes'' for each of the items listed under ''Neurological,'' thus indicating that there were no focal deficits, and indicated that she did a straight leg raise test which was negative on both legs. *Id.*

On Respondent's Assessment checklist, she checked all options, including ''Patient satisfied, doing well on current medication and treatment plan; pain condition stable'' and ''Activities of living, quality of life improved with medication.'' *Id.* at 85. Under Diagnosis, Respondent checked ''Cervicalgia,'' ''Disc Bulge'' and wrote ''L45/L51,'' ''Insomnia,'' ''Chronic Non-Malignant Pain Syndrome,'' and under ''Other, '' she added ''Ligamentum Flavum,'' ''Needs neuro consult,'' ''Ligamentum [illegible] hypertrophy,'' and ''Facet Hypertrophy.'' *Id.*

Under Plan, she again checked ''refer to PT, neurologist, neurosurgeon . . . as needed, circling ''neurologist.'' *Id.* She also placed checks marks next to multiple items, including ''urine tox screen twice a year or as needed to monitor addiction/diversion.'' *Id.* She also wrote ''next time LABS,'' ''Plan on *wean next* visit,'' ''Couldn't get MRI—cspine → will get after holiday.'' *Id.* On the line for consults, she wrote ''neurology after 1–1–12'' and ''Pt. advised if no MRI + neuro consult by Feb—2011 cannot cont meds.'' *Id.*

As for the prescriptions, Respondent circled ''Roxicodone 30 mg'' and ''#140,'' ''Xanax,'' ''1mg'' and ''#28, after which she wrote ''wean more next visit.'' *Id.* She also circled Gabapentin, and noted ''Mobic 7.5 #35'' under ''Other Meds.'' *Id.* The Encounter Summary for this visit reflects that she issued these four prescriptions to J.A. *Id.* at 82.

On January 16, 2012, J.A. returned to PBM and again saw Respondent. *Id.* at 75. He again completed the ''Patients [sic] Follow-Up Sheet'' exactly as he did as at the previous visit, circling the upper back/thoracic spine on the body diagram, did not circle any life activities that were affected by his pain, and circled 6 for his pain ''with medication'' and 10 for ''without medication.'' *Id.* at 80.

Respondent filled in the Pain History Section, on which she again indicated that J.A.'s pain was in his lower back, that it was severe, throbbing, and sharp, but did not radiate. *Id.* at 76. She checked insomnia as a co-morbidity. *Id.* And under ''New Events since Last Visit,'' she noted: ''Lost Xanax & Gabapentin script.'' *Id.*

In the ROS section, she again noted that all systems were negative, and in the PE section, she drew either checkmarks or lines next to the normal findings for each of the various items. *Id.* And next to one of the body diagrams, she circled the neck (noting ''rotation 45,'' ''Flex 45''and ''Ext 5,''), the lower back (noting ''Ext 10'' and Flex 90''), and knees (noting ''Reflexes +2''); she also noted ''Risks discussed.'' *Id.* In the Neurological section, she checked yes for each item indicating that they were normal, and in the Orthopedic section, she indicated that the straight leg raise test was negative for each leg. *Id.* at 77.

In the Assessment section, she again made checkmarks next to each of the various items including that the patient was ''doing well on current medication and treatment plan'' and that the ''Activities of living, quality of life improved with medication.'' *Id.* Under Diagnosis, she checked ''Cervicalgia,'' ''Disc Bulge'' writing ''L4/5L5S1,'' ''Insomnia,'' ''Chronic Non_malig Pain Syndrome,'' and ''Other,'' after which she wrote ''Ligamentum Flavum Hypertrophy,'' ''neuropath,'' and ''old burns on back.'' *Id.*

Under Plan, Respondent placed markings next to all but one of the line items and again circled ''neurologist'' in the line item regarding referrals.[19] She also handwrote: ''PLAN ↓ pain to cont work'' at the bottom of the page. *Id.* at 77.

As for the prescriptions, Respondent checked: ''Roxicodone'' and circled ''30 mg'' and ''#140.'' *Id.* at 78. Next to the entry for Xanax, she wrote ''last Xanax 2 days''; she also checked Xanax, next to which she wrote ''.5,'' circled ''#28,'' and wrote ''weaning.'' *Id.* Respondent noted that she was prescribing Gabapentin and Mobic 7.5 as before. *Id.* She further wrote: ''needs neuro consult,'' ''getting MRI c-spine,'' and ''Pt advised again if no MRI by Feb no more meds!!'' and circled ''Pt. advised again.'' *Id.* The Encounter Summary for the visit reflects the prescriptions for 140 Roxicodone 30 mg and 28 Xanax .5 mg, as well as the non-controlled medications. *Id.* at 75. The file also includes a Referral form signed by Respondent for an MRI on J.A.'s cervical spine. *Id.* at 83.

J.A.'s file contains a report (dated February 8, 2012) for an MRI on his cervical spine. *Id.* at 117. The report lists the following findings: a midline bulge at the C3–C4 disc ''without neuroforaminal narrowing,'' a minimal disc bulge at the C4–C5, a disc bulge at C5–C6 ''without neuroforaminal narrowing or central spinal canal stenosis,'' an ''irregularity of the endplates, anterior marginal osteophytes and a posterior bulge of the disc [at C6–C7] with extension into the left neural foramen with moderate to severe left neuroforaminal narrowing and moderate right stenosis,'' and a bulging disc at C7–T1 ''with right stenosis.'' *Id.*

On February 13, 2012, J.A. returned to PBM and again saw Respondent. *Id.* at 73. On the ''Patients [sic] Follow Up Sheet,'' J.A. circled his upper back/neck as the area of his pain, indicated that the pain affecting his ''mobility,'' but did not answer the question: ''Does the pain get worse when you move in certain ways.'' *Id.* As at the previous visits, J.A. indicated that his pain was a ''6'' ''with medication'' and a ''10'' and ''without medication.'' *Id.*

In the Pain History Follow Up section, Respondent noted the location of J.A.'s pain as both his neck and lower back, that his pain was severe, throbbing and sharp, and that the precipitating event was a ''fall'' and not the previously reported incident when he was hit by a pot. *Id.* at 67. However, Respondent indicated there were no new events since last visit. *Id.*

In the ROS section, she checked the line indicating that all were negative, and in the PE section, she placed checkmarks indicating that all exam items were normal. *Id.* On the body diagram, she circled the neck/cervical spine region and noted ''Rotation 25 L R'' and ''Worse,'' below which she wrote ''Ext: 10'' and ''Flex 45'' and ''Better.'' *Id.* She also circled the lower back and noted range of motion findings of ''Ext 10'' and ''Flex 90,'' as well as circled the knees and wrote ''Reflex +2.'' *Id.* She further noted that that J.A.'s recent MRI showed ''mild bulges C3C6,'' and ''severe stenosis at ''C6 7'' and ''C7 T1.'' *Id.* Again she wrote: ''Risks discussed.'' *Id.*

Under Neurological, she checked ''Yes'' for each exam item and wrote ''+ bilat hand strength =,'' and under Orthopedic, she indicated that the straight leg raise test was negative for both legs. *Id.* at 68. Under Assessment, she checked or drew a scribble next to each line. Under Diagnosis, she checked ''Cervicalgia,'' ''Disc Bulge'' writing ''L45/L5S1,'' ''Disc Stenosis'' writing ''C-spine,'' ''Insomnia'', ''Chronic Non-Malig Pain Syndrome,'' and ''Other,'' under which she wrote ''neuropathy'' and ''old burns on back.'' *Id.*

Under Plan, she checked or drew a scribble next to each item, and added ''Pt. wants neuro sx [surgical] opinion.'' *Id.* As for the prescriptions she checked ''Roxicodone 30 mg,'' circled ''#168,'' and added the notation: ''increase due to need to have ↓ pain to work as server.'' *Id.* at 69. She checked ''Xanax,'' wrote ''.5,'' and circled ''#28.'' *Id.* She also prescribed Gabapentin and Mobic. *Id.* The Encounter Summary for this visit lists prescriptions for 168 Roxicodone 30 mg and 28 Xanax .5 mg, as well as the other drugs. *Id.* at 66.

On March 12, 2012, J.A. returned to PBM and again saw Respondent. *Id.* at 59. On the ''Patients [sic] Follow-Up Sheet'' which accompanies the visit note,[20] J.A. circled ''yes'' in answering the questions: ''Is the pain always there?'' and ''Does the pain get worse when you move in certain ways?'' *Id.* He also circled his neck, mid-back and knee area on the body diagram to indicate his pain, and noted that his Pain Intensity ratings remained at 6 ''with medication'' and 10 ''without medication.'' *Id.* He also left blank the question regarding what life activities are affected by his pain. *Id.*

Respondent's notes in the Pain History Follow Up section, as well as her markings in the ROS and PE sections were exactly the same as those she made at J.A.'s previous visit. *Id.* at 60. As for her Range of Motion findings, with respect to J.A.'s neck, she noted: ''rotation 45 LR Better.'' *Id.* However, her other Range of Motion findings for J.A.'s neck and back, as well as her reflex test findings on his knees were exactly the same as before. *Id.* Respondent also noted ''normal hand grip'' and ''risks discussed.'' *Id.* Also, as at the previous visit, in the Neurological section, Respondent checked ''yes'' for each of the tests thus indicating that there were no focal deficits, and in the Orthopedic section, she indicated that both straight leg raise tests were negative. *Id.* at 61.

Under Assessment, Respondent again placed a mark next to each line item. *Id.* She also circled each of the same diagnoses as at the previous visit, adding the note ''c-spine'' to the diagnosis of ''Disc Bulge.'' *Id.* Under Plan, Respondent placed a mark next to each item. *Id.* As for the prescriptions, she issued the same prescriptions of 168 Roxicodone 30 mg and 28 Xanax .5 mg (as well as Gabapentin and Mobic) as before. *Id.* at 62; *see also id.* at 59 (Encounter Summary listing prescriptions).

Next to the medication list, Respondent also wrote: ''Goal: cont to work as chef'' and ''needs meds to control pain so He can work + support Kids.'' *Id.* Yet in the Pain History Follow Up, Respondent had circled ''N'' (rather than ''Y'') in the space for noting whether the patient had ''Kids''; she also left the blank the space for listing the ''Ages'' of any kids. *Id.* at 60.

On April 9, 2012,[21] J.A. returned to PBM and again saw Respondent. Respondent's notations were the same

[19] Respondent did not, however, place any mark next to the line stating: ''Continue meds, patient understands importance of weaning meds to minimum effective dose.''

[20] J.A. dated this Patient Follow Up Sheet ''2/12/12.'' GE 18, at 64. However, this document was placed next to the visit notes for J.A.'s visit of March 12, 2012, and the evidence shows that J.A.'s February visit occurred on February 13, 2012.

[21] There is no Patient Follow Up Sheet in the file which is dated April 9, 2012. There are, however, two copies of the Follow Up Sheet dated 5/7/12. GE 18 at 53, 49.

as to the location, character, levels and precipitating event of J.A.'s pain, and the co-morbidity of insomnia. *Id.* at 56. So too, Respondent circled ''N,'' indicating that J.A. did not have kids. *Id.* While Respondent wrote ''none'' as to whether there were new events since J.A.'s last visit, she added: ''Patient Had long weekend—server for High Holy Days,'' below which she wrote ''Risk discussed.'' *Id.*

Under ROS, Respondent again indicated that all systems were negative, and under PE, she again placed marks indicating normal findings for her PE. *Id.* On the body diagram, she circled the neck (writing ''Rotation 25 L R more''), the lower back (writing ''Ext 10'' and ''Flex 45''), and the knees (writing ''reflex +2''). *Id.* Under Neurological, she checked ''Yes'' for each item indicating that there were no focal deficits, and under Orthopedic, she indicated that she had done a negative straight leg raise test on both legs. *Id.* at 57.

As before, in the Assessment section, Respondent made a mark next to each item. *Id.* She also listed the diagnoses of ''Cervicalgia,'' ''Disc Bulge'' after which she wrote ''C spine'' and ''L45/L4S1,'' ''Disc Stenosis'' after which she wrote ''Cspine,'' ''Insomnia,'' ''Chronic Non-Malig Pain Syndrome,'' and ''Other'' after which she wrote ''neuropathy 2'' and ''Back Burns.'' *Id.*

Under Plan, Respondent placed a mark next to each of the line items. *Id.* Respondent also wrote: ''goal cont to work as chef & support kids.'' *Id.* at 58. Respondent reissued to J.A. prescriptions for 168 Roxicodone 30 mg, 28 Xanax .5 mg, as well as Gabapentin and Mobic. *Id.* at 58; *see also id.* at 55 (Encounter Summary).

On May 7, 2012, J.A. returned to PBM and again saw Respondent. On the ''Patients [sic] Follow-Up Sheet,'' J.A. circled various areas of his body where he felt pain and against rated his pain as a 6 ''with medication'' and a 10 ''without medication.'' *Id.* at 49. However, J.A. did not answer any of the other questions on the form. *Id.*

In the Pain History Follow Up section of the visit note, Respondent made the same notations as before, with the exception of noting under ''New Events,'' ''heavy hours server.'' *Id.* at 46. While the body diagram is not visible on this form, in the same place where the body diagram appears on the other forms, Respondent drew three circles with arrows and noted ''Rotation L 25 R 45'' near the top circle, ''Reflex + 2,'' ''Ext 10'' and ''Flex 90'' near the middle circle, and ''Reflex +2'' near the bottom circle; she also noted ''Hand grip + 2.'' *Id.*

Respondent documented the exact same findings in the Neurological and Orthopedic sections of the visit note, and placed either a checkmark of vertical line through each item in the Assessment section. *Id.* at 47. Under Diagnosis, Respondent added ''Anxiety'' and ''Muscle Spasm C spine'' to her previous diagnoses of ''Cervicalgia,'' ''Disc Bulge C-Spine L45/,'' ''Disc Stenosis C-spine,'' ''Insomnia,'' ''Chronic Non-Malig Pain Syndrome,'' and Neuropathy 2'' and ''Back Burn.'' *Id.*

As for her Plan, Respondent placed a check mark next to the line stating: ''wt lost, smoking cessation, reduce salt and caffeine, F/U with PCP,'' circling the latter and writing ''CXR.'' *Id.* She also placed a checkmark next to the line for various types of referrals. *Id.* As for the other items, she either drew a diagonal or vertical line next to the item. *Id.* And on the last page, Respondent indicated that she was prescribing 168 Roxicodone 30 mg and 28 Xanax .5 mg, along with Flexeril (a non-controlled muscle relaxant) and Mobic. *Id.* at 48. *See also id.* at 45 (Encounter Summary listing prescriptions).

On June 4, 2012, J.A. returned to PBM and saw Respondent for the final time.[22] On the ''Patients [sic] Follow-Up Sheet,'' J.A. circled the neck, upper back and right knee on the body diagram to indicate where he felt pain. *Id.* at 40. He again indicated that his pain was a 6 ''with medication'' and a 10 ''without medication.'' *Id.* J.A. did not, however, answer any of the form's other questions nor indicate if he was ''satisfied with [his] current medication.'' *Id.*

In the Pain History Follow Up section, Respondent noted that J.A.'s pain was in his neck and lower back, that it was throbbing but not radiating, that it was precipitated by a ''fall,'' but did not check whether the ''[s]everity of pain'' was ''mild,'' ''moderate,'' or ''severe.'' *Id.* at 37. Respondent indicated that J.A.'s pain level was at the same numeric levels (6 with medication, 10 without) as he circled on the Follow-up Sheet. *Id.* She again indicated ''N'' for whether J.A. had kids, and in the line for listing ''[n]ew events,'' wrote: ''still very heavy hours as server.'' *Id.*

In the ROS section, Respondent indicated that all were negative, and in the PE section, she indicted that each item was normal. *Id.* On the body diagram, Respondent circled the neck (writing ''Rotation R 45 L 25'' and ''Flex 25 Ext 10''), the lower back (writing ''Ext 10 Flex 45 worse''), the right elbow (writing ''Reflexes + 2 bilat), and both knees (writing ''Reflex +2''). *Id.* Respondent also wrote: ''Hand grip +2.'' *Id.* Under Neurological, Respondent circled ''yes'' for each exam item thus indicating that there were no focal deficits, and under Orthopedic, she indicated a negative finding for the straight leg raise test on both legs. *Id.* at 38.

Under Assessment, Respondent circled the words ''Patient satisfied'' and ''Patient taking meds as prescribed,'' and she wrote ''yes'' next to the line stating ''[a]ctivities of living, quality of life improved with medications.'' *Id.* She also placed check marks next to the remaining three items. *Id.*

As for her Diagnosis, Respondent checked (and notated) the exact same diagnoses as she did at J.A.'s previous visit. *Id.* In the Plan section, Respondent either placed check marks or circled portions of each item; as with the previous visit, she circled ''F/U with PCP'' and wrote ''needs CXR-pt advised.'' *Id.* And at the bottom of the page, she wrote: ''goal Cont to work + support family.'' *Id.* Respondent then documented the same medications as she prescribed at the previous visit: 168 Roxicodone 30 mg, 28 Xanax .5 mg, and the non-controlled drugs Flexeril and Mobic. *Id.* at 39; *see also id.* at 30 (copies of prescriptions). J.A. also signed a Patient Compliance Instruction sheet on that visit.[23] *Id.* at 41.

The Government's Expert reviewed J.A.'s patient file and found that the medical history and physical examinations of J.A. were ''inadequate and that it was not reasonable for Registrant to rely on the evaluations of other providers at'' PBM. GE 24, at 14. The Expert also found that Respondent ''failed to conduct an adequate physical examination or take a satisfactory medical history,'' noting that ''she relied on the superficial checklists which are insufficient for evaluating the types of complaints that J.A. communicated.'' *Id.* The Expert further noted that on February 13, 2012, Respondent ''prescribed additional narcotics without any medical justification'' when

[22] When J.A. returned to PBM on June 27, 2012, he saw a different doctor.

[23] The file also contains a sheet titled ''June 13 2012 audit page.'' GE 18, at 44. This document lists handwritten notes pertaining to the dates that MRIs and labs were ordered and received, the dates of two UDSs and the results for one of the tests, blood pressure and pulse readings at J.A.'s visits, the date records were received (which lists only the May 2001 ER records), and ''Referral[s] Out.'' *Id.*

Notably, the Referrals included the following notes: (1) ''2/28/11—recommend ortho eval,'' (2) ''11/21/11—consult neurology,'' (3) ''5/7/12—F/U—PCP needs CXR,'' with an arrow pointing to (4) ''6/27/12—pt broke & can't have done.'' *Id.* Respondent's initials appear at the bottom of the page. *Id.*

she increased J.A.'s prescription for oxycodone from 140 tablets to 168 tablets ''based solely on the bald statement that the patient needed 'to have less pain to work.' '' *Id.*

The Expert also found that J.A.'s patient file ''contain[s] no evidence that [Respondent] addressed the effect of pain on J.A.'s physical and psychological function.'' *Id.* at 15. The Expert further explained that ''that the checklist is devoid of any explanation for how J.A.'s pain affected his social activities, mobility, work, exercise or sleep.'' *Id.*

Next, the Expert found that Respondent's ''treatment plan was wholly inadequate,'' because it ''consisted of only a checklist of recommendations.'' *Id.* He further observed that J.A.'s file ''is devoid of any evidence that any of the recommendations were either discussed or followed.'' *Id.* The Expert noted that Respondent ''recommended Yoga and other exercise, fish oil and glucosamine/chondroitin sulfate,'' and ''also stated [that] she will ''refer to PT, Neurologist, neurosurgeon, orthopedist, psychiatrist, addiction specialist as needed.'' *Id.* The Expert then explained that ''[t]here is no evidence that any of these alternative measures were attempted [or] that any referrals were made.'' *Id.* at 15.

Finally, the Expert also found that Respondent ''ignored numerous red flags for diversion'' with respect to J.A. *Id.* These included that ''J.A. tested positive for methadone even though his last prescription for methadone had been issued five months earlier,'' and ''that he reported that he lost his Xanax, which was not discussed or resolved in the patient file.'' *Id.* The Expert further noted that J.A. ''presented a Florida Identification card instead of a valid driver's license'' and that ''[t]his raises questions as to whether . . . [J.A.] obtained the cars solely for the purpose of establishing temporary residence in Florida in order to obtain controlled substances'' *Id.* The Expert thus concluded that J.A. ''was clearly at risk for misusing his medications and posed a risk for medication misuse and/or diversion'' and that Respondent ''failed to monitor the patient's compliance in medication usage and failed to give special attention to J.A.'' *Id.* The Expert further concluded that the controlled substance prescriptions Respondent issued to J.A. ''lacked a legitimate medical purpose and were issued outside of the usual course of professional practice.'' *Id.* at 15.

Patient D.B.

Patient D.B., a 66-year-old resident of Okeechobee, Florida, first presented at PMB on January 31, 2012 with a chief complaint of back pain which started ''3 yrs ago.'' GE 14, at 13. D.B. noted that there was no precipitating event, and that his pain level was a 2 ''with medication'' and a 7 ''without medication.'' *Id.* He further noted that he had undergone chiropractic procedures and that he had tried or been on anti-inflammatories, Dilaudid, Percocet, and Xanax. *Id.* He answered ''yes'' to the question: ''Have you seen any other doctors for this pain?'' *Id.* And on an exhaustive list of ''symptoms you have or have had in the past year,'' D.B. checked nervousness, back and hip, high blood pressure, appendicitis, arthritis, heart disease, hepatitis, high cholesterol and a pacemaker, among other things. *Id.* at 15. D.B. was also subjected to a drug screen which was negative for all items tested including ''Opiates/Morphine'' and ''Oxycodone.'' *Id.* at 10.

On the visit note, another physician indicated that D.B. had a three-year history of middle and lower back pain as well as right and left hip pain, that the pain was moderate, severe, sharp and tingling; the physician also noted that D.B.'s pain ''off meds'' was an 8 and ''on meds'' a 3. *Id.* at 31. As to co-morbidities, the physician checked anxiety and insomnia. *Id.* As to previous pain management treatment, the physician circled only ''medication'' and next to the word ''PM Center,'' wrote ''[n]one.'' *Id.*

As to what made D.B.'s pain worse, the physician placed checkmarks next to ''lifting,'' ''bending'' and ''sitting''; she also circled ''standing.'' *Id.* As for what made D.B.'s pain better, the physician checked only resting. *Id.* The physician also placed checkmarks to indicate that the pain affected D.B.'s ''sleep,'' ''mood,'' ''work,'' ''daily activities,'' ''energy,'' and ''relationships.'' *Id.* After checking that D.B.'s was quality of life was ''worse'' off medications and ''better'' on them, the physician circled ''none'' for D.B.'s history of smoking and drug use, and circled ''occ'' for his alcohol use. *Id.*

Under current meds, the physician listed several non-controlled drugs including aspirin, Plavix, Diovan, and Amlodipine, but no controlled substances. *Id.* Under past imaging, the physician checked ''CT,'' placed a checkmark in the space for inserting the date of a lumbar scan but no date and placed a check to indicate that a thoracic spine scan had been done but left blank the date.[24] *Id.*

Under ROS, the physician indicated that all were negative, and under PE, the physician indicated normal findings with the exception of ''mildly obese'' on the line for Abd. *Id.* at 32. The physician documented four Range of Motion findings (''F 60, Ext 10, RL 65 and LL 65''), documented a positive straight leg raise test on each leg, and found no focal deficits with respect to any of the neurological exam items. *Id.* The physician further documented that D.B. ''was treated for 72 HR w/Perocet by PMD and referred to Pain Clinic for further management of pain. Was offered surgery by his Orthopod but declined for now.'' *Id.*

Under Assessment, the physician placed a check mark next to each item. *Id.* Under Diagnosis, she checked ''Hypertension,'' ''Lumbago,'' ''Sciatica,'' ''Chronic Non-Malig Pain Syndrome,'' and ''Other,'' next to which she wrote ''Schmorl's Nodes' and ''multi level osteophytes.'' [25] *Id.* at 33. Under Plan, placed a checkmark next to each item and wrote ''No NSAIDS, PT is on Plavix and ASA [aspirin].'' *Id.* The physician also noted that she was prescribing 112 Lortab 10/500 (hydrocodone/acetaminophen). *Id.; see also id.* at 30 (Encounter Summary).

On February 28, 2012, D.B. returned to PBM and saw the same physician. *Id.* at 54. D.B. noted on the ''Patients [sic] Follow-Up Sheet'' that his pain was always there, that it affected his social activities and sleep, that his pain was a 3 ''with medication'' and a 7 ''without medication.'' *Id.*

In the Pain History section of the visit note, the physician noted that D.B.'s pain was located in his lower back and radiated, as well as in his thigh, leg and knee, that the pain was severe, and its duration was ''5 yrs.'' *Id.* at 50. The physician also noted that D.B.'s pain was precipitated by a motor vehicle accident; she also checked insomnia as a co-morbidity. *Id.* She further noted the same pain ratings with and without medication as D.B. had listed on the ''Patients [sic] Follow-Up Sheet.'' *Id.* As for new activities since his last visit, Respondent noted that D.B.'s pacemaker had been checked one week ago and that D.B. ''says activity level has increased, less anxiety.'' *Id.* The physician also noted that DC complained of ''inadequate pain control.'' *Id.*

Under ROS, the physician indicated that all were negative, and under PE, the

[24] The physician also noted the frequency of D.B.'s visits to his primary care physician and cardiologist, as well as listed various conditions he had such as ''HTN,'' ''COPD,'' ''Hx of Syncope,'' and that he had a pacemaker. GE 14, at 31.

[25] On the Encounter Summary, the physician noted an additional diagnosis of ''Insomnia due to Medical Condition Classified Elsewhere.'' GE 14, at 30.

physician circled normal findings for ''Heent,'' ''Chest,'' ''Cor,'' ''Abd,'' and ''Neuro/psych'' but made no markings as to ''Skin,' ''Ext,'' and ''Gait.'' *Id.* As for the Neurological exam, the physician indicated that each exam item was normal with no focal deficits. *Id.* However, under Orthopedic, she made no findings as to either straight leg raise tests or range of motion. *Id.*

In the Assessment section, the physician left unchecked each line item, and in the Diagnosis section, the physician checked ''Insomnia,'' ''Lumbago,'' ''Sciatica,'' ''Chronic Non-Malig Pain Syndrome,'' and ''Other,'' next to which she wrote ''Osteophytosis,'' ''Schmorl's nodes,'' and ''OA.'' The physician then placed a checkmark next to each item in the Plan section and noted that she was discontinuing the Lortab and changing the prescription to 112 dosage units of Roxicodone 30 mg (one pill four times a day) ''for better pain control.'' *Id.* at 51–52. The physician also issued a prescription for 15 dosage units of Xanax 1 mg for ''insomnia/anxiety,'' and a prescription for 28 dosage units of Colace, a non-controlled drug, for constipation. *Id.* at 52; *see also id.* at 56 (Encounter Summary).

On March 5, 2012, D.B. returned to PBM and saw Respondent who noted that ''Pt here 2–28–12'' and that he had ''brought back'' both the oxycodone and Xanax prescriptions because he ''couldn't get scripts filled st Lucie + Okeechobee three dif pharmacies where he lived.'' *Id.* at 57. Respondent documented that she did a PE which was comprised of a straight leg raise test which was negative, that his range of motion of his lumbar spine was 45 degree in flexion and 10 degrees in extension, and that his patella reflexes were ''+2.'' *Id.* Respondent listed diagnoses of OA (osteoarthritis), HTN (hypertension), IDDM (insulin dependent diabetes mellitus), Osteopenia, Schmorl's nodes, and Kyphosis. *Id.* As for her ''Plan,'' Respondent listed ''CT Lumbar,'' and ''Renew meds [discontinue] oxycodone.'' *Id.* Respondent then listed prescriptions for 112 du of Dilaudid 8 mg, 15 Xanax 1 mg, and Colace. [26] *Id.*

D.B.'s file included a report of a CT scan on his lumbar spine which was done on March 15, 2012. *Id.* at 58. The report lists the radiologist's impression as: ''[b]ulging annuli as discussed. Prominent bulging annulus and mild lumbar spinal stenosis at L4–5. Right paracentral calcified disc protrusion/spur at the L5–S1 level.'' *Id.*

On March 27, 2012, D.B. returned to PBM and again saw Respondent. *Id.* at 64. On the ''Patients [sic] Follow-Up Sheet,'' D.B circled his lower back as the location of his pain, reported that the pain was always there and got worse when he moved in certain ways, and that it affected his social activities, mobility and sleep. *Id.* He indicated that the intensity of his pain was 4 ''with medication'' and 8 ''without medication.'' *Id.*

In the visit note's Pain History Follow Up section, Respondent noted that D.B.'s lower back pain was severe, throbbing, and sharp and had been precipitated by a motor vehicle accident in 2003. *Id.* at 60. She checked insomnia as a co-morbidity, noted that his pain scale off meds was ''8'' and on meds was ''4,'' that his quality of life ''Off medications'' was ''worse'' and his quality of life ''ON medications'' was ''better.'' *Id.* Also, following the words: ''Psych visits/SS Disability past 5 yr,'' she circled ''Y.'' *Id.*

Under ''ROS,'' she indicated that all were negative. *Id.* Under ''PE,'' she placed a variety scribbles next to each item. *Id.* On the body diagram, she circled the thoracic spine (writing ''Kyphosis''), the lumbar spine (noting Range of Motion findings of ''Ext 10 Flex 90''), and the knees (noting ''reflexes +2''); she also noted ''−SLR'' as well as ''[r]isks discussed.'' *Id.* Also, under ''Neurological,'' she checked each items as normal with no focal deficits. *Id.* at 63.

In the Assessment section, Respondent indicated that D.B. was ''satisfied, doing well on current medication and treatment plan,'' that he was ''taking meds as prescribed,'' that he ''denied any drug charges or arrests since [his] last visit,'' and that the ''diagnosis and treatment plan are justified and based on diagnostic results, history and physical exam.'' *Id.* As for her Diagnosis, Respondent checked: ''Disc Protrusion'' and noted ''L5S1,'' ''Disc Stenosis'' and noted ''L45,'' ''Hypertension,'' ''Chronic Non-Malignant Pain Syndrome,'' and under ''Other,'' she wrote ''pacer,'' ''OA,'' ''IDDM'' (diabetes) and ''osteophytes.'' *Id.*

Under Plan, she placed check marks next to each item and handwrote ''Add glucosamine/chondroitin.'' *Id.* On the medications page, Respondent noted that ''April 2 is 28 days'' and that she was prescribing 112 du of Dilaudid 8mg and 15 du of Xanax 1 mg, as well as Ibuprofen 400 mg and Colace 100 mg. *Id.* at 62. The Encounter Summary states, however, that both the Dilaudid and Xanax prescriptions were not to be ''fill[ed] before [A]pril 2, 2012.'' *Id.* at 61.

On April 24, 2012, D.B. returned to PBM and again saw Respondent. *Id.* at 70. On the ''Patients [sic] Follow-Up Sheet,'' D.B. circled his lower back, again indicated that his pain was ''always there'' and got worse when he ''move[d] in certain ways,'' and that it affected his Social Activities and Mobility; he also indicated that his pain was a 4 ''with medication'' and an 8–9 ''without medication.'' *Id.* D.B. did not, however, indicate that the pain affected his ''Sleep.'' He also checked that he was ''satisfied with [his] current medication'' and ''would not like to change it,'' rather than the alternative choice of ''not satisfied'' and ''would like to discuss changes.'' *Id.*

In the visit note's Pain History Follow Up section, Respondent filled in the form with few changes since the last visit, except to add ''anxiety'' to the list of co-morbidities and noted that D.B. was ''Able to fill Dilaudid.'' *Id.* at 66. Under ROS, Respondent again indicated that all were negative, and under PE, Respondent checked or circled normal findings for each exam item. Following the words: ''Psych visits/SS Disability past 5 yr,'' she circled ''Y.'' *Id.*

On the body diagram, Respondent circled the thoracic spine (writing ''Kyphosis''), the lumbar spine (noting Range of Motion findings of ''Flex 90'' and ''Ext 10''), and the knees (noting ''Reflex +2''). *Id.* She also placed checkmarks next to each of the Neurological exam items indicating that there were no focal deficits and noted that the straight leg raise test was negative for both legs. *Id.* at 68.

As for her Assessment, Respondent either checked or placed a scribble for each item, and in the Diagnosis section, Respondent checked and added each of the same conditions as before with the exception of Hypertension which she did not check. *Id.* at 68. Under Plan, Respondent checked or drew a vertical line next to each item and again wrote an entry for glucosamine/chondroitin. *Id.* As for the medications, Respondent again prescribed 112 du of Dilaudid 8 mg, noted that she was discontinuing Xanax, and added 28 Klonopin 1 mg ''[e]very [e]vening at [s]leep [t]ime.'' [27] *Id.* at 67, 69.

On May 31, 2012, D.B. returned to PBM and again saw Respondent. *Id.* at 72. On the ''Patients [sic] Follow-Up Sheet,'' he again reported that the pain was ''always there,'' got worse when he

[26] The Encounter Summary shows that Respondent also prescribed Ibuprofen. GE 14, at 59.

[27] She also noted that she was prescribing Colace and Ibuprofen, although the latter drug is not listed in the Encounter Summary. *Compare* GE 14, at 69, *with id.* at 67.

''moved in certain ways'' and affected his ''[s]ocial [a]ctivities'' and ''[m]obility.'' *Id.* As to the intensity of his pain, D.B. reported that it was an ''8'' ''with medication'' and a ''3'' ''without medication.'' *Id.* D.B., however, indicated that he was satisfied with his current medication and would not like to change it. *Id.*

In the Pain History Follow Up section of the visit note, Respondent again noted that D.B. suffered from lower back pain that was throbbing and sharp, and was precipitated by a 2003 motor vehicle accident. *Id.* at 76. Respondent checked ''anxiety'' and ''insomnia'' as co-morbidities,'' and as to D.B.'s pain level, Respondent recorded that ''off meds'' it was 8, and ''on meds'' it was ''4.'' *Id.* Following the words: ''Psych visits/SS Disability past 5 yr,'' she circled ''Y.'' *Id.*

Under ROS, Respondent checked the line to indicate that all were negative, and under PE, she again placed a checkmark or scribbled over the various normal findings for each exam item. *Id.* On the body diagram, she again circled the thoracic spine (writing Kyphosis), the lumbar spine (noting ROM findings of ''Flex 90'' and ''Ext 10''), and the knees (noting ''Reflex +2). *Id.* In the Neurological section, Respondent again indicated that each item was normal with no focal deficits, and in the Orthopedic section, she indicated that the straight leg raise test was negative on each leg. *Id.* at 74.

Under Assessment, Respondent either placed a checkmark or vertical line through each item. *Id.* As for her diagnosis, Respondent added ''Anxiety'' and ''Insomnia'' to the previous diagnoses of ''Disc Protrusion L5S1,'' ''Disc Stenosis L45,'' ''Chronic Non-Malig Pain Syndrome,'' and ''Other,'' next to which she added the same diagnoses of ''OA,'' ''Pacer,'' ''IDDM,'' and Osteophytes.'' *Id.*

As for her Plan, Respondent either made a checkmark or drew a vertical line next to each item. *Id.* As for the medication, she noted that she was issuing prescriptions for 112 du of Dilaudid 8 mg, 56 Klonopin 1 mg ''for anxiety,'' 28 Ambien .5 mg (zolpidem, a schedule IV drug) ''for insomnia,'' as well as Colace and Ibuprofen. *Id.* at 75; *see also id.* at 77 (Encounter Summary). Of note, the Klonopin prescription was double the quantity of previous prescription and the Ambien was a new prescription.

On June 28, 2012, D.B. returned to PBM and again saw Respondent. *Id.* at 78. He again reported that his pain was ''always there,'' that it ''got worse when [he] move[d] in certain ways,'' and affected his ''Social Activities'' and ''Mobility.'' *Id.* D.B. reported that his pain was a ''4'' with medication and a ''9'' without medication, and that he was ''satisfied'' with his ''current medication'' and ''would not like to change it.'' *Id.*

In the Pain History section of the visit note, Respondent again documented that D.B.'s pain was in his lower back, that it was severe and throbbing, and that it was precipitated by a 2003 motor vehicle accident. *Id.* at 83. She again noted co-morbidities of anxiety and insomnia, as well as that he had ''psych visits/ss disability'' in the past five years, that his only previous pain management treatment were ''meds,'' and that ''lifting'' and ''sitting/standing in one position too long'' made his pain worse, and that the pain affected his ''sleep,'' ''mood,'', ''daily activities,'' and ''energy,'' although ''sleep'' made his ''pain better.'' *Id.* Respondent also noted that his pain level was 8 ''off meds'' (D.B. had reported it as a ''9'') and a 4 ''on meds.'' *Id.* She also indicated that his ''quality of life OFF medications'' was ''worse'' and his ''quality of life ON medications'' was ''better.'' *Id.* She also noted that a CT exam on ''3–12 [had shown] stenosis.'' *Id.*

Under ROS, Respondent checked that all were negative, and under Physical Exam, she circled normal findings for each item. *Id.* at 80. However, she also noted ''+ palmar erythema.'' *Id.* Under Neurological, Respondent found each exam item to be normal with no focal deficits. *Id.* Under Orthopedic, Respondent circled ''+'' and ''30–60'' degrees for the straight leg raise test on each leg; noted that D.B.'s range of motion for his lumbar spine was ''45'' in flexion and ''10'' in extension; that Compression and Valsalva tests on his cervical spine were both negative; that a Kemps test on his lumbar spine was positive on the right side; and that his gait was normal. *Id.*

In the Assessment section, Respondent placed checkmarks to indicate that D.B. was satisfied and understood how to take current medication, that he would take medication as prescribed and had no side effects, that his life activities and quality of life were improved with medications, that medication storage issues were addressed, and that he lived in a stable condition with no drug related activity or persons in his home. *Id.* at 81. As for her diagnoses, Respondent checked anxiety, back pain, disc bulge, disc protrusion, disc stenosis, hypertension, insomnia, chronic non-malig pain syndrome, and other, under which she ''pacer'' and ''CAD [coronary artery disease] + stent.'' *Id.*

Under Plan, Respondent noted that ''PCP obtained/referred for . . . HTN'' and ''chemistry screen due from PCP.'' *Id.* As for the medications, Respondent checked Klonopin (circling ''1mg'' and ''#56'') and Ambien (circling ''5 mg'' and ''#28''), as well as Colace; she also wrote 112 Dilaudid 8 mg. *Id.; see also id.* at 82 (copies of prescriptions); *id.* at 93 (Encounter Summary).

The file also contains a release for medical records (including progress notes, a prescription profile and diagnostic reports) from a particular doctor which D.B. executed on June 28, 2012. *Id.* at 91. However, the release was not faxed to the other doctor until July 24, 2012. *Id.* at 92.

On July 23, 2012, D.B. saw Respondent a final time. *Id.* at 85. On the ''Patients [sic] Follow-Up Sheet,'' D.B. did not answer if the pain was ''always there.'' *Id.* at 86. However, he claimed that the pain affected his ''Social Activities,'' ''Mobility,'' and ''Sleep,'' as well as that it got ''worse when [he] move[d] in certain ways?'' *Id.* D.B. rated his pain as a ''2'' with medication and ''8–9'' without medication. *Id.* He also checked that he was ''satisfied with [his] current medication'' and ''would not like to change it.'' *Id.*

In the Pain History section of the progress note, Respondent noted that the pain was in D.B.'s lower back, that it was severe, throbbing, and sharp, and that it was precipitated by a 2003 motor vehicle accident. *Id.* She again indicated that ''lifting'' and ''sitting, standing in one position too long'' made his pain worse and that sleep made his pain better. *Id.* As for what the pain affected, she place checkmarks next to ''sleep'' and ''daily activities''; she also drew short diagonal lines next to ''mood'' and ''energy.'' *Id.* As for D.B.'s numeric pain rating, Respondent noted ''8'' for ''off meds'' and a ''4'' for ''on meds,'' which was different than the level (2) D.B. had circled. *Id.* at 85. Respondent also circled ''Y'' for ''Pysch visits/SS Disability,'' and noted that D.B.'s only previous pain management treatment was ''meds.'' *Id.*

Respondent made no checkmarks next to any of the items under ROS, and under PE, she again circled normal findings for each of the exam areas. *Id.* at 88. Under Neurological, Respondent circle normal findings with no focal deficits for each exam item. *Id.* Under Orthopedic, Respondent circled ''+'' and ''30–60'' degrees for the straight leg raise test on each leg; noted that D.B.'s range of motion for his lumbar spine was ''45'' in flexion and ''10'' in extension; that

Compression and Valsalva tests on his cervical spine were both negative; that a Kemps test on his lumbar spine was positive on the right side; and that his gait was normal. *Id.*

In the Assessment section, Respondent placed checkmarks to indicate that D.B. was satisfied and understood how to take current medication, that he would take medication as prescribed and ''reported no side effects,'' that his life activities and quality of life were improved with medications, that medication storage issues were addressed, and he lived in a stable condition with no drug related activity or persons in his home. *Id.* at 89. As for her diagnoses, Respondent checked anxiety, back pain, disc bulge, disc protrusion, disc stenosis, hypertension, insomnia, chronic non-malig pain syndrome, and other, under which she wrote ''pacer'' and ''CAD [coronary artery disease] + stent.'' *Id.*

Under Plan, she again noted ''PCP obtained/referred for . . . HTN,'' as well as ''chemistry screen due next visit.'' *Id.* She again prescribed 112 du of Dilaudid 8 mg, 56 du of Klonopin 1 mg for anxiety, 28 tablets of Ambien 5 mg for insomnia, and Colace. *Id.* at 84, 89.

The Expert reviewed D.B.'s patient's file and found that ''the medical history and physical examinations of D.B.'' that were done by the other doctor at PBM were ''inadequate and that it was not reasonable to rely on [those] evaluations.''' GE 24, at 9. The Expert also found that Respondent did not ''conduct[] an adequate physical examination or t[ake] a satisfactory medical history,'' and that she ''relied on the superficial checklists which are insufficient for evaluating the types of complaints that D.B. communicated.'' *Id.* He found that Respondent ''prescribed both clonazepam for anxiety and zolpidem for insomnia, [but] fail[ed] to record any information whatsoever to justify these prescriptions other than baldly noting that D.B. *had* anxiety and insomnia.'' *Id.* The Expert also noted that on May 31, 2102, Respondent increased D.B.'s clonazepam prescription ''without any justification.'' *Id.*

Continuing, the Expert found that Respondent's ''records contain no evidence that [she] addressed the effect of pain on D.B.'s physical and psychological function,'' and that ''[t]he checklist is devoid of any explanation for how D.B,'s pain affected his social activities, mobility, work, exercise or sleep.'' *Id.* He also found that Respondent's ''treatment plan was wholly inadequate and, again, consisted only of a checklist of recommendations'' and that there was no ''evidence that any of the recommendations were either discussed or followed.'' *Id.* The Expert also noted that while Respondent ''recommended 'glucosamine/Chondroitin Sulfate,' and stated that she will 'refer to PT, neurologist, neurosurgeon, orthopedist, psychiatrist, psychiatrist, addiction specialist as needed[,]' [t]here is no evidence that any of these alternative measures were attempted, [or] that any referrals were made.'' *Id.*

The Expert further found that Respondent ''ignored numerous red flags for diversion'' in her treatment of D.B., who lived ''approximately 95 miles from'' PBM in Okeechobee, Florida. *Id.* at 10. The Expert specifically noted that there was ''nothing in the medical file to explain why D.B. would travel so far to obtain prescriptions.'' *Id.* He also noted that ''D.B. came to [PBM] as an opiate naïve patient, having tested negative for *all* controlled substances on January 31, 2012, and having no prescription history.'' The Expert noted that D.B. ''was given a large quantity of narcotic[s]'' (112 du of hydrocodone) even though at the first visit he reported that his pain level ''was '2' while medicated [and] he was currently on *no* medication.'' *Id.* The Expert also noted that, notwithstanding that D.B. was prescribed hydrocodone, his pain level had increased to 3, and ''despite an enormous increase in the amount of opioid medication that Respondent prescribed on March 5, 2012,'' when she issued him a prescription for 112 du of Dilaudid 8 mg, his pain level with medication increased yet again to 4. *Id.*

The Expert further noted that D.B.'s chart contain inconsistent statements as to the duration of his pain, with D.B. reporting at his first visit (Jan 31, 2012) that he had the pain for three years, which he then changed at his second visit (Feb. 28, 2012) to five years (having been precipitated by an auto accident), only to claim at his fourth visit (Mar. 27, 2012) that it was of nine years duration. *Id.* And the Expert noted that when D.B. told her that he was unable to fill the oxycodone and Xanax prescriptions at a pharmacy in his home town as well as in Port St. Lucie, Respondent ''failed to investigate why [he] was allegedly refused service by three different pharmacies.'' *Id.*

The Expert thus concluded that ''these red flags indicate to me that Registrant failed to monitor the patient's compliance in medication usage and failed to give special attention to [him], who was clearly at risk for misusing his medications and posed a risk for medication misuse and/or diversion.'' *Id.* The Expert further concluded that the controlled substance prescriptions Respondent issued to D.B. ''lacked a legitimate medical purpose and were issued outside of the usual course of professional practice.'' *Id.* at 15.

Other Patients

In light of my findings with respect to the UC, D.G., J.A., and D.B., I deem it unnecessary to make detailed findings with respect to the remaining patients. I note, however, that the Expert concluded that Respondent ignored numerous red flags for diversion with each of these patients, including D.H. and J.B., who lived in Panama City, Florida, more than 500 miles from PBM, as well as W.B., who resided in Southport, Florida, which is approximately 547 miles from PBM. GE 24, at 7–8, 12–13. With respect to these patients, the Expert noted that there was ''no information in the medical records to explain why [they] would travel such an extraordinarily long distance to receive what amounted to be superficial, substandard medical care.'' *Id.* at 13–14.

With respect to each of the seven chart review patients, the Expert opined that Respondent ''repeatedly ignored readily identifiable red flags (aberrant behaviors) and continued to issue prescriptions for controlled substances despite unresolved red flags for abuse and/or diversion.'' *Id.* at 15. The Expert also opined that Respondent ''failed to prescribe in accordance with the level of care, skill and treatment recognized by a reasonably prudent physician under similar circumstances.'' *Id.*

Summing up, the Expert concluded that Respondent:

> failed to conduct a complete medical history and examination proportionate to the diagnosis that justified the treatment she provided. She failed to adequately document the (1) nature and intensity of the pain; (2) current and past treatments for pain; (3) underlying or coexisting disease and conditions; (4) the effect of pain on the patients' physical and psychological function. [She] failed to perform an adequate review of previous medical records, previous diagnostic studies, and each patient's history of alcohol and/or substance abuse. [She] failed to develop a written plan for assessing each patient's risk for aberrant drug-related behavior and monitor that risk. [She] failed to document an individualized treatment plan containing objectives to be used to determine treatment success . . . [and] failed to (1) adjust the drug therapy to the individual needs of the patient; (2) consider another's treatment modalities other than prescriptions for controlled substances; and (3) discuss the risk of abuse and addiction, as well as physical dependence and its consequences. *Id.* at 15–16.

Discussion

Section 304(a) of the Controlled Substances Act (CSA) provides that a registration to ''dispense a controlled substance * * * may be suspended or revoked by the Attorney General upon a finding that the registrant * * * has committed such acts as would render his registration under section 823 of this title inconsistent with the public interest as determined under such section.'' 21 U.S.C. 824(a)(4). With respect to a practitioner, the Act requires the consideration of the following factors in making the public interest determination:

(1) The recommendation of the appropriate State licensing board or professional disciplinary authority.

(2) The applicant's experience in dispensing * * * controlled substances.

(3) The applicant's conviction record under Federal or State laws relating to the manufacture, distribution, or dispensing of controlled substances.

(4) Compliance with applicable State, Federal, or local laws relating to controlled substances.

(5) Such other conduct which may threaten the public health and safety. *Id.* § 823(f).

''These factors are * * * considered in the disjunctive.'' *Robert A. Leslie, M.D.,* 68 FR 15227, 15230 (2003). I ''may rely on any one or a combination of factors, and may give each factor the weight [I] deem[ ] appropriate in determining whether a registration should be revoked.'' *Id.; see also Volkman* v. *DEA,* 567 F.3d 215, 222 (6th Cir. 2009). While I must consider each factor, I am ''not required to make findings as to all of the factors.'' *Volkman,* 567 F.3d at 222; see also *Hoxie* v. *DEA,* 419 F.3d 477, 482 (6th Cir. 2005); see also *Morall* v. *DEA,* 412 F.3d 165, 173–74 (D.C. Cir. 2005).

''In short, this is not a contest in which score is kept; the Agency is not required to mechanically count up the factors and determine how many favor the Government and how many favor the registrant. Rather, it is an inquiry which focuses on protecting the public interest; what matters is the seriousness of the registrant's or applicant's misconduct.'' *Jayam Krishna-Iyer,* 74 FR 459, 462 (2009). Accordingly, as the Tenth Circuit has recognized, findings under a single factor can support the revocation of a registration. *MacKay* v. *DEA,* 664 F.3d 808, 821 (10th Cir. 2011).

The Government has the burden of proof. *See* 21 CFR 1301.44(e). Moreover, even where a Respondent waives her right to a hearing, the Government must provide substantial evidence to support the allegations and its proposed sanction. *Gabriel Sanchez,* 78 FR 59060, 59063 (2013).

The Government contends that the evidence with respect to Factors Two, Four, and Five establishes that Respondent's registration is inconsistent with the public interest and should be revoked.[28] Specifically, it argues that Respondent prescribed controlled substances to the UC and at least seven other patients without a legitimate medical purpose and/or outside the usual course of professional practice, and that she issued prescriptions without medical justification, without proper examinations, and in violation of both state and Federal law.

Factors Two and Four—Respondent's Experience in Dispensing Controlled Substances and Record of Compliance With Applicable Controlled Substance Laws

Under a longstanding DEA regulation, a prescription for a controlled substance is not ''effective'' unless it is ''issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice.'' 21 CFR 1306.04(a). This regulation further provides that ''an order purporting to be a prescription issued not in the usual course of professional treatment . . . is not a prescription within the meaning and intent of [21 U.S.C. 829] and . . . the person issuing it, shall be subject to the penalties provided for violations of the provisions of law related to controlled substances.'' *Id.; see also* Fla. Stat. § 893.05(1) (''A practitioner, in good faith and in the course of his or her professional practice only, may prescribe . . . a controlled substance[.]''); *id.* § 893.13(1)(a) (rendering it ''unlawful for any persons to sell, manufacture, or deliver . . . a controlled substance'' except as authorized by the Florida Comprehensive Drug Abuse Prevention and Control Act, Fla. Stat. §§ 893.01 *et seq.*); *id.* § 458.331(q) (providing that prescribing ''any controlled substance, other than in the course of the physician's professional practice,'' is grounds for ''disciplinary action'').[29]

As the Supreme Court has explained, ''the prescription requirement . . . ensures patients use controlled substances under the supervision of a doctor so as to prevent addiction and recreational abuse. As a corollary, [it] also bars doctors from peddling to patients who crave the drugs for those prohibited uses.'' *Gonzales* v. *Oregon,* 546 U.S. 243, 274 (2006) (citing *United States* v. *Moore,* 423 U.S. 122, 135, 143 (1975)); *United States* v. *Alerre,* 430 F.3d 681, 691 (4th Cir. 2005), *cert. denied,* 574 U.S. 1113 (2006) (prescription requirement stands as a proscription against doctors acting not ''as a healer[,] but as a seller of wares'').

Under the CSA, it is fundamental that a practitioner must establish and maintain a legitimate doctor-patient relationship in order to act ''in the usual course of . . . professional practice'' and to issue a prescription for a ''legitimate medical purpose.'' *Paul H. Volkman,* 73 FR 30629, 30642 (2008), *pet. for rev. denied,* 567 F.3d 215, 223–24 (6th Cir. 2009); *see also Moore,* 423 U.S. at 142–43 (noting that evidence established that the physician exceeded the bounds of professional practice, when ''he gave inadequate physical examinations or none at all,'' ''ignored the results of the tests he did make,'' and ''took no precautions against . . . misuse and diversion''). The CSA, however, generally looks to state law to determine whether a doctor and patient have established a legitimate doctor-

[28] As to Factor One, while Respondent is currently prohibited from practicing medicine, this is not the result of action taken by the Florida Board of Medicine but a condition of bail imposed by the Broward County Court. *See* Respondent's Motion for Extension of Time Pursuant to 21 CFR 1316.47(b). Moreover, there is no evidence that the Florida Department of Health has either made a recommendation to the Agency with respect to Respondent, or taken any disciplinary action against Respondent. *See* 21 U.S.C. 823(f)(1).

However, even assuming that Respondent currently possesses authority to dispense controlled substances under Florida law and thus meets this requirement for maintaining her registration, *see Frederic Marsh Blanton,* 43 FR 27616 (1978), this finding is not dispositive of the public interest inquiry. *Cf. Mortimer Levin,* 57 FR 8680, 8681 (1992) (''[T]he Controlled Substances Act requires that the Administrator . . . make an independent determination [from that made by state officials] as to whether the granting of controlled substance privileges would be in the public interest.''). Accordingly, this factor is not dispositive either for, or against, the Government's proposed sanction of revocation. *Paul Weir Battershell,* 76 FR 44359, 44366 (2011) (citing *Edmund Chein,* 72 FR 6580, 6590 (2007), *pet. for rev. denied, Chein* v. *DEA,* 533 F.3d 828 (D.C. Cir. 2008)).

As to Factor Three, there is no evidence that Respondent has been convicted of an offense under either federal or Florida law ''relating to the manufacture, distribution or dispensing of controlled substances.'' 21 U.S.C. 823(f)(3). However, there are a number of reasons why even a person who has engaged in criminal misconduct may never have been convicted of an offense under this factor, let alone prosecuted for one. *Dewey C. MacKay,* 75 FR 49956, 49973 (2010), *pet. for rev. denied, MacKay* v. *DEA,* 664 F.3d 808 (10th Cir. 2011). The Agency has therefore held that ''the absence of such a conviction is of considerably less consequence in the public interest inquiry'' and is therefore not dispositive. *Id.*

[29] Florida law defines the term ''prescription'' to mean, in relevant part, ''an order for drugs . . . written, signed, or transmitted by word of mouth, telephone, telegram, or other means of communication by a duly licensed practitioner licensed by the laws of the state to prescribe such drugs . . . issued in good faith and in the course of professional practice.'' Fla. Stat. § 893.02(22).

patient relationship. *Volkman,* 73 FR 30642.

By regulation, the Florida Board of Medicine has adopted ''Standards for the Use of Controlled Substances for the Treatment of Pain.'' Fla. Admin. Code r. 64B8–9.013. The Board has explained that these ''standards are not intended to define complete or best practice, but rather to communicate what the Board considers to be within the boundaries of professional practice.'' *Id.* r.64B8–9.013(1)(g) (2011–2012). At the time of the events at issue here, the Board's standards provided as follows:

(a) Evaluation of the Patient. A complete medical history and physical examination must be conducted and documented in the medical record. The medical record shall document the nature and intensity of the pain, current and past treatments for pain, underlying or coexisting diseases or conditions, the effect of the pain on physical and psychological function, and history of substance abuse. The medical record also shall document the presence of one or more recognized medical indications for the use of a controlled substance.

(b) Treatment Plan. The written treatment plan shall state objectives that will be used to determine treatment success, such as pain relief and improved physical and psychosocial function, and shall indicate if any further diagnostic evaluations or other treatments are planned. After treatment begins, the physician shall adjust drug therapy, if necessary, to the individual medical needs of each patient. Other treatment modalities or a rehabilitation program may be necessary depending on the etiology of the pain and the extent to which the pain is associated with physical and psychosocial impairment.

(c) Informed Consent and Agreement for Treatment. The physician shall discuss the risks and benefits of the use of controlled substances with the patient, persons designated by the patient, or with the patient's surrogate or guardian if the patient is incompetent. The patient shall receive prescriptions from one physician and one pharmacy where possible. If the patient is determined to be at high risk for medication abuse or have a history of substance abuse, the physician shall employ the use of a written agreement between physician and patient outlining patient responsibilities, including, but not limited to:

1. Urine/serum medication levels screening when requested;

2. Number and frequency of all prescription refills; and

3. Reasons for which drug therapy may be discontinued (*i.e.,* violation of agreement).

(d) Periodic Review. Based on the individual circumstances of the patient, the physician shall review the course of treatment and any new information about the etiology of the pain. Continuation or modification of therapy shall depend on the physician's evaluation of the patient's progress. If treatment goals are not being achieved, despite medication adjustments, the physician shall reevaluate the appropriateness of continued treatment. The physician shall monitor patient compliance in medication usage and related treatment plans.

(e) Consultation. The physician shall be willing to refer the patient as necessary for additional evaluation and treatment in order to achieve treatment objectives. Special attention must be given to those pain patients who are at risk for misusing their medications and those whose living arrangements pose a risk for medication misuse or diversion. The management of pain in patients with a history of substance abuse or with a comorbid psychiatric disorder requires extra care, monitoring, and documentation, and may require consultation with or referral to an expert in the management of such patients.

(f) Medical Records. The physician is required to keep accurate and complete records to include, but not be limited to:

1. The complete medical history and a physical examination, including history of drug abuse or dependence, as appropriate;

2. Diagnostic, therapeutic, and laboratory results;

3. Evaluations and consultations;

4. Treatment objectives;

5. Discussion of risks and benefits;

6. Treatments;

7. Medications (including date, type, dosage, and quantity prescribed);

8. Instructions and agreements;

9. Drug testing results; and

10. Periodic reviews. Records must remain current, maintained in an accessible manner, readily available for review, and must be in full compliance with [Fla. Admin. Code] rule 64B8–9.003 . . . and [Fla. Stat.] Section 458.331(1)(m). . . .

Id. r.64B8–9.013(3)(a)–(f) (2011–2012).

The Florida Board has further explained that it ''will judge the validity of prescribing based on the physician's treatment of the patient and on available documentation, rather than on the quantity and chronicity of prescribing. The goal is to control the patient's pain for its duration while effectively addressing other aspects of the patient's functioning, including physical, psychological, social, and work-related factors.'' *Id.* r. 64B8–9.01391)(g) (2011–2012).[30]

Applying the Board's standards, the Government's Expert concluded that Respondent failed to establish a sufficient doctor/patient relationship with the UC. GE 24, at 3. He further opined that the controlled substance prescriptions issued by Respondent to the UC lacked a legitimate medical purpose and were issued outside of the usual course of professional practice. *Id.; see* 21 CFR 1306.04(a). Indeed, with respect to the UC, there is sufficient evidence even apart from the Expert's declaration to support the conclusion that Respondent violated 21 CFR 1306.04(a) when she prescribed controlled substances to the UC. *See T.J. McNichol,* 77 FR 57133, 57147 (2011) (discussing cases finding violations of 21 CFR 1306.04(a), 21 U.S.C. 841, and similar state laws without requiring expert testimony), *pet. for rev. denied,* 537 Fed. Appx. 905 (11th Cir. 2013).

The Expert found that Respondent failed to make ''a serious inquiry into the cause of the patient's pain'' and failed to take a complete medical history of the UC's pain. *Id.* at 3. The Expert explained that ''in a valid doctor/patient relationship, a physician must inquire into whether the pain is the result of an injury or another disease process'' and that this ''was not sufficiently done'' as Respondent's questioning was limited to determining that the UC was a stunt man and had not been in a car accident and that there was ''no critical injury at all.'' *Id., see also* GE 7, at 3 (transcript of UC's visit with Respondent on May 31, 2012.) Indeed, the evidence shows that the UC simply complained of stiffness and muscle soreness from both his work and doing ''heavy squats''; he also denied having numbness or tingling in his legs. GE 7, at 3–4.

The Expert further noted that while the UC had stated that he had seen as many as six other doctors for his pain and provided signed releases for his medical records, those records were not obtained. GE 24, at 3. According to the Expert, as part of the history, ''it is important to review the records of other physicians who have treated the patient.'' *Id.* The Expert further noted that Respondent ''never inquired as to the treatment UC may have received prior to coming to [PBM]'' and did not ''discuss any non-narcotic treatment [he] may have received from any other doctor at PBM.'' *Id.* at 4. Also, in his declaration, the UC stated that Respondent never asked him if he had any history of substance abuse. GE 25, at 5.

The Expert also found that Respondent failed to conduct an adequate physical examination of the UC, noting that he ''failed to demonstrate pain sufficient to justify the repeated prescribing of controlled

[30] *See also* Fla. Admin. Code r. 64B8–9.003(2) (''A licensed physician shall maintain patient medical records in English, in a legible manner and with sufficient detail to clearly demonstrate why the course of treatment was undertaken.''); *id.* r. 64B8–9.003(3) (''The medical record shall contain sufficient information to identify the patient, support the diagnosis, justify the treatment and document the course and results of treatment accurately, by including, at a minimum, patient histories; examination results; test results; records of drugs prescribed . . . . ; reports of consultations and hospitalizations; and copies of records or reports or other documentation obtained from other health care practitioners at the request of the physician and relied upon by the physician in determining the appropriate treatment of the patient.'').

substances, especially strong opioid medications such as'' oxycodone 30 mg. GE 24, at 3. Indeed, at his first visit, the UC reported that on a scale of 0 to 10, his pain level without medication was a 2. GE 11, at 36. Yet on the visit note, Respondent indicated that the UC's pain was severe and noted that his pain level ''off meds'' was a 5. *Id.* at 33. Respondent also indicated that the UC's pain was both ''throbbing'' and ''sharp.'' *Id.* Yet at no point during the UC's visit did he complain of having ''throbbing'' or ''sharp'' pain. Thus, the evidence supports the conclusion that Respondent falsified the UC's medical record by documenting symptoms which the UC never complained of and a higher pain level than what the UC complained of.

Moreover, as the video shows, Respondent's physical exam was limited to having the UC bend over; sit down and turn his head from side to side; placing a stethoscope on his chest; having him sit down, extend his legs and squeeze his calves and ask if there was any tenderness; and striking his knees with a neurologic hammer while his feet were still placed on the floor. GE 3, V–0002, at 14:14:24–14:14:35 and 14:18:34–14:19:18; *see also* GE 25, at 2–3. Yet the visit note includes findings based on a variety of tests which were not done including testing his cranial nerves, doing a sensory exam, testing his reflexes for both the upper and lower extremities, testing his muscle strength both upper and lower, and doing a straight leg raise test on each leg. *Compare* GE 11, at 33–34 (visit note), *with* GE 3, at V–0002, at 14:14:24–14:14:35 and 14:18:34–14:19:18. Indeed, the video shows that the various tests Respondent performed as part of the physical exam lasted less than one minute.

The Expert also found that Respondent diagnosed Respondent as having muscle spasms, without any evidence. Indeed, the UC never complained of spasms and the video shows that Respondent never palpated the UC's lower back. Moreover, Respondent diagnosed the UC has having anxiety and issued a clonazepam prescription to treat this condition, even though the UC told Respondent that ''[o]nce in a while'' he would ''take a little bit of Xanax to sleep,'' but he thought he could ''probably work without it.'' GE 11, at 4, *see also id.* at 27, 34. Also, in his declaration, the UC stated that during his visits to PBM, he ''never disclosed that [he] suffered from anxiety.'' GE 25, at 3.

The Expert concluded that Registrant ''failed to determine and/or document the effect of pain on UC's physical and psychological function, [because] there is no documentation in the record to show that she made any attempt to adequately address this important standard of pain management.'' GE 24, at 4.

The Expert also found that Respondent ''failed to create and/or document a sufficient treatment plan.'' *Id.* The Expert explained that despite UC's history of treatment at PBM and receipt of ''prescriptions for controlled substances on prior occasions, [Respondent] recommended no further diagnostic evaluations or other therapies.'' *Id.* The Expert then observed that the UC's ''MRI . . . failed to demonstrate serious enough pathology for him to receive the large amounts of controlled substances that were prescribed.'' *Id.* According to the Expert, ''[b]ulging discs can usually be addressed by other means such as physical therapy, exercise, work strengthening programs, abdominal core training, anti-inflammatories, and at times, injections such as nerve blocks with corticosteroids,'' but that ''[n]one of these options was offered or discussed by'' Respondent. *Id.* The Expert then opined that ''[i]gnoring these options constitutes an inferior, if not non-existent, treatment plan.'' *Id.*

The Expert also found that the transcripts and recordings of UC's visits showed that Respondent ''herself doubted there was a legitimate medical need to prescribe the large amounts of opioid medications that were prescribed.'' *Id.* As the Expert noted, during the UC's May 31, 2012 visit, Respondent told the UC that his MRI showed '' 'nothing too terrible,' '' that '' 'a bulge kind of doesn't mean anything' '' and that she would not 'give narcotics for spasms.' '' *Id.* (citing GE 7, at 4–5). The Expert also observed that ''[o]n the second visit, [Respondent] said she 'certainly wouldn't just give pain medicines and narcotics so [his] working out is better.' '' *Id.* (quoting GE 9, at 5).

The Expert also concluded that there was no legitimate medical justification for the amount of oxycodone prescribed to the UC because, prior to the May 31, 2012 visit, the UC had not been seen by a pain clinic physician since January 18, 2012, and was, in all likelihood, opiate naïve at the May 31, 2012 visit. *Id.* at 5. As found above, at the May 31, 2012 visit, the UC was subjected to a drug test. GE 25, at 1. However, the UC tested negative for all controlled substances including opiates/morphine, oxycodone, and benzodiazepines. GE 11, at 39. According to the Expert, ''[p]rescribing 112 thirty milligram tablets of oxycodone in this instance was without medical justification and dangerous.'' *Id.*

With respect to the July 16, 2012 visit, the Expert noted that Respondent increased the amount of the oxycodone prescription from 112 to 140 dosage units without any medical justification. As the evidence shows and the Expert found, while the UC reported that his pain without medication was a ''2,'' he changed it only after being prompted by Respondent. *See* GE 9, at 4–5; GE 24, at 5. Also, on the ''Patients [sic] Follow-Up Sheet,'' the UC did not indicate that the pain affected any of the five listed activities and when Respondent asked if the pain affected his ''work, sleep, mood, etc,'' the UC initially answered ''no'' before adding that it affected his ''recovery time from working out.'' *Compare* GE 11, at 29, *with* GE 9, at 5. This prompted Respondent to state that ''we certainly wouldn't just give pain medicines and narcotics so your [sic] working out is better,'' to which the UC replied that he understood. GE 9, at 5. Thereafter, Respondent coached the UC to state that the pain affected his work.[31] *Id.*

Respondent also falsified the medical record at this visit by indicating that the UC's pain was made worse by ''sitting, standing in one position too long,'' as nothing in the record shows that the UC made such a claim. GE 11, at 25. And she again falsified the medical record by documenting findings for various neurological and orthopedic examination items (including a positive straight leg raise test on his left leg) when she never performed the tests. *Compare* GE 11, at 26 (visit note), *with* GE 5, V–0003, at 15:45:36–15:46:47.

Moreover, while looking at the UC's MRI, Respondent again noted that ''bulges we don't treat'' but that there was ''encroachment or . . . narrowing of the disc'' and that ''*I better put that down.*'' GE 9, at 8 (emphasis added). As with Respondent's coaching the UC to change both his pain rating and the type of activities that his pain affected from his answer of ''working out,'' this supports the inference that Respondent was looking for any justification that she could place in the chart for issuing the oxycodone prescription. Still later

[31] When asked at his second visit whether the pain affected his sleep, the UC replied ''Work'' and he had not circled ''sleep'' as being affected by his pain on the ''Patients [sic] Follow-Up Sheet'' he filled in at this visit. GE 11, at 29. As the Expert concluded, ''the record is devoid of any medical evidence justifying the need for prescribing clonazepam.'' GE 24, at 6. The Expert also found that by failing to retrieve or cancel the unfilled May 31, 2012 prescription at the July 16, 2012 visit, Respondent effectively enabled the UC to obtain twice the amount as directed by the physician when she gave him a second prescription. *Id.*

during the physical exam, the UC did not complain of any pain in his back but only of having tight hamstrings; he also again told Respondent that when he had back stiffness, this was caused by doing ''heavy squats.'' GE 9, at 12. Moreover, the UC was two weeks late for the second visit with Respondent and told her that while he had run out of medication, he was able to get some from a friend.[32] *Id.* at 10.

Based on the above, I conclude that Respondent knew that the UC was not a legitimate pain patient. I further conclude that Respondent acted outside of the usual course of professional practice and lacked a legitimate medical purpose in issuing each of the controlled substance prescriptions to the UC. 21 CFR 1306.04(a).

As for D.G., I also conclude that Respondent acted outside of the usual course of professional practice and lacked a legitimate medical purpose when she prescribed controlled substances to him. 21 CFR 1306.04(a). As found above, D.G. resided in Niceville, Florida, which is located nearly 600 miles from Respondent's clinic. Yet there is no evidence in any of D.G.'s records that Respondent inquired as to why D.G. was travelling these distances to obtain controlled substances from PBM.

Moreover, D.G.'s chart shows that while he obtained large prescriptions for multiple controlled substances at his first two visits at PBM, he then did not return to PBM until July 2011, seven months after his previous visit. To be sure, D.G.'s file contains a pharmacy printout showing that D.G. had obtained both oxycodone and alprazolam on multiple occasions (beginning on January 20, 2011 and ending on June 9, 2011) from a different physician who was located in Palm Beach County and yet filled each of the prescriptions in Santa Rosa Beach, Florida, which is in Walton County and near Niceville. Yet D.G.'s file contains no evidence that any inquiry was made as to why D.G. had returned to PBM. Nor is there any evidence that this other physician was contacted to determine whether D.G. was still seeing him.

While there is no evidence that D.G. obtained prescriptions at PBM at his July 6, 2011 visit, on September 7, 2011 he returned to PBM and denied having received prescription medications from other physicians as well as other sources in the last 30 days. Yet D.G. tested positive for oxycodone. Again, nothing in the chart reflects that this inconsistency was resolved. While Respondent did not treat D.G. at this visit, this information was nonetheless in his chart.

There are likely multiple legitimate pain management practices closer to Niceville, Florida than 600 miles (the distance to PBM) or 566 miles (the distance to Lake Clark Shores, where the other prescribing physician was located). Indeed, when D.G. finally presented evidence that he had made an appointment to treat his hypertension, he made the appointment with a free clinic in Destin, Florida, which is near Niceville. Yet the pharmacy profile showed that he paid cash for every prescription. GX 17, at 120–22. Likewise, given D.G.'s positive test for oxycodone while claiming that he had not obtained prescription medications from other sources clearly shows that he was non-compliant with the Pain Management Agreement he entered at his first visit.

I hold that the evidence that D.G. was travelling nearly 600 miles (one way) to obtain prescriptions at PBM, his disappearance for months only to later return, and his aberrant drug test (all of which are apparent in the chart) supports the conclusion that Respondent subjectively believed that there was a high probability that D.G. was either abusing controlled substances and/or diverting them to others. *See JM Pharmacy Group, Inc.,* 80 FR 28667, 28672 (2015) (citing *Global-Tech Appliances, Inc.,* v. *SEB S.A.,* 563 U.S. 754, 769–70 (2011)) . As D.G.'s chart contains no evidence showing that Respondent attempted to resolve any of these issues with him, I further hold that she ''deliberately failed'' to acquire actual knowledge that D.G.'s purpose in seeking the prescriptions was to either abuse them or divert them to others. I thus conclude Respondent acted outside of the usual course of professional practice and lacked a legitimate medical purpose when she prescribed controlled substances to D.G. 21 CFR 1306.04(a).

The Expert's review of D.G.'s chart buttresses this conclusion. As he explained, it was not reasonable for Respondent to rely on the evaluations done by the other providers at PBM. Indeed, at his first visit, D.G. tested negative for all drugs. As the Expert opined with respect to the UC, D.G. was likely opiate naïve. Yet Dr. Sanchez proceeded to issue D.G. prescriptions for both 150 oxycodone 30 mg and 60 oxycodone 15 mg and 60 Xanax 2 mg. This is a quantity of oxycodone even greater than the quantity Respondent prescribed to the UC at the first visit (112 du of 30 mg), which the Expert explained was without medical justification and dangerous. GE 24, at 5; *see also Roxicodone: Package Insert and Label Information, Dosage Information-Initial Dosage* (''Initiate treatment with ROXICODONE in a dosing range of 5 to 15 mg every 4 to 6 hours for pain). Thus, this dosage was more than 2.5 times the maximum recommended starting dose.

Moreover, as the Roxicodone Package Insert explains, ''[c]oncomitant use of opioids with benzodiazepines or other central nervous system (CNS) depressants, including alcohol, may result in profound sedation, respiratory depression, coma, and death.'' *Id.* (Risks from Concomitant Use with Benzodiazepines or Other CNS Depressants). Yet, Dr. Sanchez also prescribed Xanax in its strongest dosage form and neither of the visit notes contains a diagnosis of anxiety or findings that would support such a diagnosis. Indeed, at D.G.'s second visit, Sanchez drew a ''0'' next to sleep and wrote ''Ok'' next to ''Overall Mood.'' GE 17, at 126. The willingness of Dr. Sanchez to prescribe to these drugs to an opioid naive patient strongly suggests that PBM was not a legitimate medical practice but a pill mill.

Nor do the visit notes prepared by the other PBM physicians who prescribed to D.G. suggest otherwise. Indeed, it is telling that the pre-printed medication lists on which the PBM doctors would note the prescriptions they issued, includes only a single narcotic—Roxicodone—and only a single dosage form—30 mg—which just happens to be the strongest dosage of immediate release oxycodone available.

Moreover, the Expert found that Respondent ''failed to conduct an adequate physical examination or take a satisfactory medical history of D.G.,'' in

[32] The Expert also cited this as evidence of Respondent's failure to properly monitor the UC's compliance with his medication usage. GE 24, at 5. According to the Expert, ''before prescribing so much additional oxycodone [as she did at the July 16, 2012 visit], Respondent should have had a discussion with [UC] about his need for more medication and made specific inquiries to determine if and how [his] pain had increased.'' *Id.* The Expert thus concluded that Respondent failed to inquire or determine whether there was a legitimate medical need for the additional medication, and failed to adjust the quantity and frequency of the dose of oxycodone according to the intensity and duration of the pain and failed to justify the additional prescription on clear documentation of unrelieved pain. *Id.* And the Expert concluded that the UC demonstrated he was at risk for misusing his medications and that Registrant failed to give him the special attention required. *Id.* The Expert also concluded ''that there was serious doubt as to whether treatment goals were being achieved. Yet, there was no attempt by [Respondent] to evaluate the appropriateness of continued treatment except to increase the amount of narcotics and create a means by which [the UC] could fill his prescriptions without raising the legitimate concerns of pharmacists.'' *Id.* at 4. The Expert opined that ''there was an insufficient review of the course of treatment and the prescriptions provided by [Respondent] to [the UC] [were] inconsistent with [her] evaluation.'' *Id.* at 4–5.

that ''she relied on . . . superficial checklists which are insufficient for evaluating the types of complaints [neck and back pain] that D.G. communicated.'' *Id.* at 13. The Expert also found that D.G.'s ''records contain no evidence that [Respondent] addressed the effect of pain on D.G.'s physical and psychological function,'' even though the Florida Board's rule requires that a physician document ''the effect of the pain on physical and psychological function.'' Fla. Admin Code r. 64B8–9.013(1)(g). As the Expert observed, ''the checklist is devoid of any explanation for how D.G.'s pain affected his social activities, mobility, work, exercise or sleep.'' *Id.* (citing GE 23, at 39–42, 49–52, 57–60, 62–63, 65–67).

The Expert similarly found that Respondent's ''treatment plan was wholly inadequate and . . . consisted only of a checklist of recommendations.'' *Id.* The Expert noted that there is no evidence that any of the recommendations were either discussed or followed. *Id.* He also noted that while Respondent placed a checkmark suggesting that referrals to physical therapy and other specialist physicians were part of her plan for D.G., there is no evidence ''that any referrals were made.'' *Id.* at 13–14.

Finally, the Expert also found that Respondent ''prescribed additional narcotics without any medical justification.'' *Id.* at 13. The Expert specifically noted that ''on April 19, 2012, she added a prescription for [56 du of morphine sulfate [30 mg], stating that . . . D.G. needed more medication in order to continue his restaurant business and that his pain had increased at work.'' *Id.* The Expert noted that ''[t]his contradicts statements D.G. made that same day, in which he declared he was satisfied with his current medication.'' *Id.* Moreover, on the ''Patients [sic] Follow-Up Sheet'' he completed at his April 19, 2012 visit, D.G. reported the exact same pain level with medication—''3'' on a scale of 0 to 10—as he did at his previous visit. *Compare* GE 17, at 61, 71. D.G.'s record contains no further explanation as to how his pain at work had increased and how it affected his ability to function. *See generally* GE 17.

I therefore conclude that the record supports a finding that Respondent acted outside of the usual course of professional practice and lacked a legitimate medical purpose in issuing the controlled substance prescriptions to D.G. 21 CFR 1306.04(a).

As for J.A., the evidence shows that he tested positive for opiates/morphine, methadone, and oxycodone at his October 24, 2011 visit to PBM, which immediately preceded his first visit with Respondent (Nov. 21, 2011). Notably, J.A.'s records showed that his previous visit to PBM was three months earlier on July 22, 2011, at which he received prescriptions for oxycodone and methadone for a 28-day supply. Moreover, at the October 24, 2011 visit, J.A. denied having seen any ''other medication prescribing pain docs.'' GE 18, at 98. While J.A.'s drug test was clearly aberrant, the October 24, 2011 visit note contains no documentation that J.A. was questioned as to why he was positive for these drugs when he had not been to the clinic in three months and denied seeing any ''other medication prescribing pain doctor doctors.''

More importantly, in the visit note Respondent prepared for J.A.'s November 21, 2011 visit, she noted that his October 24, 2011 drug screen was positive for opiates, methadone and oxycodone, and yet there is no evidence that Respondent questioned J.A. as to why he was positive for these drugs given his absence from the clinic and his having denied seeing other pain doctors. Here again, this evidence supports a finding that Respondent was willfully blind to J.A.'s likely purpose in seeking the prescriptions. She nonetheless issued him prescriptions for 140 Roxicodone 30 mg and 28 Xanax 1 mg, the latter being prescribed for anxiety.[33]

As to the latter prescription, while Respondent checked ''insomnia'' but not ''anxiety'' as one of her diagnoses, Respondent made no findings to support either diagnosis. Indeed, on the ''Patients [sic] Follow-Up Sheet,'' J.A. did not circle any of the six items (which included social activities and sleep) as being affected by his pain. Moreover, the Expert found that Respondent failed to conduct an adequate physical examination or take a satisfactory medical history to properly evaluate J.A.'s complaints. GE 24, at 14. The Expert also found that J.A.'s file ''contains no evidence that [Respondent] addressed the effect of pain on J.A.'s physical and psychological function.'' *Id.* at 15.

The Expert further found that Respondent's treatment plan was wholly inadequate. *Id.* Indeed, while in the Plan section of the visit note, Respondent checked the line for referrals and circled the word ''neurology'' to suggest that she was making such a referral, there is no evidence that any such referral was ever made or that J.A. ever went to a neurologist.[34] *Id.* Moreover, while in the December 19, 2011 visit note, Respondent wrote that if J.A. did not obtain a ''neuro'' consultation ''by Feb 2011'' [sic], he ''cannot cont. meds,'' GE 18, at 85, Respondent continued to prescribe both Roxicodone 30 mg and Xanax at each of J.A.'s monthly visits which occurred through June 4, 2012. While Respondent did eventually reduce J.A.'s Xanax prescription to the .5 milligram dosage form, at no point did she make findings to support her diagnosis of anxiety or insomnia.

Moreover, notwithstanding J.A.'s failure to comply with her instruction that if he did not obtain a ''neuro consult'' by his February visit, she would not continue the prescriptions, at the February 2012 visit, Respondent increased his Roxicodone 30 prescription to 168 dosage units. *Id.* at 69. On the visit note, Respondent noted: ''increase due to need to have ↓pain to work as server.'' *Id.* The Expert explained that Respondent's decision to increase the prescription was ''based solely on the bald statement that the patient needed 'to have less pain to work.' '' GE 24, at 14. The Expert further explained that this statement did not provide a ''medical justification'' to support the increase in the prescription. *Id.*

Of further note, while at J.A.'s first visit to PBM in February 2011, he reported that he had previously been treated by other physicians for his pain and provided signed release forms, GE 18, at 4, 19; the only such records obtained (other than an MRI report) was for his ER visit in May 2001, a decade earlier. As the Expert explained in discussing the UC's file, ''[i]n completing a sufficient medical history, it is important to review the records of other physicians who have treated the patient.'' GX 24, at 3. Of further note, Respondent saw J.A. eight times over the course of seven months and yet never obtained records from treating physicians other than those who

[33] Respondent noted under ''new events since last visit'' that J.A. reported that he lost his Xanax and gabapentin prescriptions on his January 16, 2012 visit with Respondent, and Respondent again noted that he ''lost Xanax 2 days'' on the medications sheet. GE 18, at 76, 78. While there is no other notation by Respondent that she discussed the lost medications with J.A., she wrote him a new prescription for 28 tablets of .5 mg Xanax along with prescriptions for the other medications.

[34] Even at J.A.'s February 2012 visit, which purportedly was the cut-off date for him to obtain a neurological consultation, Respondent noted: ''Pt. wants neuro sx [surgical] opinion.'' GE 18, at 68. There is, however, no notation as to why J.A. never got this opinion in the course of his seeing Respondent.

J.A.'s chart also states that at his first visit, the attending physician recommended that he obtain an orthopedic evaluation. GE 18, at 133. Here too, there is no evidence that J.A. ever obtained an orthopedic evaluation.

attended J.A. during the May 2001 ER visit.

Accordingly, I find that the record supports the conclusion that Respondent acted outside of the usual course of professional practice and lacked a legitimate medical purpose in prescribing controlled substances to J.A. 21 CFR 1306.04(a).

Turning to Respondent's prescribing to D.B., as the Expert noted, the history of the origin of his pain changed multiple time during the course of his visits to PBM. Significantly, at his initial visit, D.B. noted that his pain had started had three years earlier and he answered ''No'' as to whether there was ''an inciting event[] (Such as a car accident).'' GE 14, at 13. One month later, his pain was of five years duration and had been precipitated by a car accident. *Id.* at 50. And one month later, when Respondent saw him for the second time,[35] the duration of his pain had increased to nine years. *Id.* at 60. The Expert found D.B.'s changing story regarding the origin of his pain to be highly suspicious. GE 24, at 10. And the Expert also found it suspicious that D.B. resided in Okeechobee, Florida, approximately 95 miles from PBM, and yet was travelling to PBM to obtain prescriptions. *Id.* As the Expert noted, there is ''nothing in the medical file to explain why D.B. would travel so far to obtain [the] prescriptions.'' *Id.* Moreover, the Expert also noted that while D.B. told Respondent that the three pharmacies would not fill the oxycodone 30 and Xanax prescriptions he obtained from a different doctor one week earlier, Respondent ''also failed to investigate why [he] was allegedly refused service by'' the pharmacies. *Id.*

The Expert further noted that at D.B.'s initial visit, he reported that his pain level was a 2 with medication and his drug screen results showed that he was negative for all drugs including oxycodone and opiates/morphine. GE 24, at 10; *see also* GE 14, at 10, 13. According to the Expert, ''having tested negative for all controlled substances and having no prescription history, D.B. was an opioid naïve patient.'' GE 24, at 10. While a different doctor prescribed ''a large quantity of narcotics'' (112 du of hydrocodone 10 mg), when D.B. returned for his second visit, he then complained of that pain level on medication had increased to ''3.'' *Id.* Moreover, even after Respondent changed his prescription to 112 Dilaudid 8 mg, which the Expert characterized as ''an enormous increase in the amount of opioid medication'' over his prior hydrocodone prescription, at his next visit, D.B. reported that his pain had increased to ''4'' with medication. *Id.*

Based on the ''red flags'' of the distance D.B. was travelling, the changes in his story of how and when his pain originated, his story of being unable to fill the prescriptions at three different pharmacies, and his report of increasing pain levels even after being prescribed large and increasing dosages of narcotics, the Expert concluded that D.B. ''was clearly at risk for misusing his medications and posed a risk for medication misuse and/or diversion'' and that Respondent ''failed to monitor [D.B.'s] compliance in medication usage and failed to give special attention to'' him. *Id.; see also* Fla. Admin. Code r.64B8–9.013(1)(e). Moreover, based on these circumstances, I find that Respondent subjectively believed that there was a high probability that D.B. was seeking the medications to either abuse them or divert them to others, and deliberately failed to acquire actual knowledge of his purpose in obtaining the prescriptions.

The Expert also found that ''the medical history and physical examinations of D.B.'' that were done by the other doctor at PBM were ''inadequate and that it was not reasonable [for Respondent] to rely on [those] evaluations.' '' GE 24, at 9. The Expert further found that Respondent did not ''conduct[ ] an adequate physical examination or t[ake] a satisfactory medical history,'' and she ''relied on the superficial checklists which are insufficient for evaluating the types of complaints that D.B. communicated.'' *Id.*

Moreover, as the Expert explained in discussing the UC, in determining a patient's pain history, ''it is important to review the records of other physicians who have treated the patient.'' *Id.* at 3. While D.B. noted on the form he completed at his first visit to PBM that he had ''seen . . . other doctors for this pain,'' GE 14, at 13, his file contains no records from any physician who treated him for his back pain.[36] *See generally* GE 14.

The Expert also found that Respondent's ''records contain no evidence that [she] addressed the effect of pain on D.B's physical and psychological function,'' and that ''[t]he checklist is devoid of any explanation for how D.B,'s pain affected his social activities, mobility, work, exercise or sleep.'' GE 24, at 9. The Expert further found that Respondent ''prescribed both clonazepam for anxiety and zolpidem for insomnia, [but] fail[ed] to record any information whatsoever to justify these prescriptions other than baldly noting that D.B. *had* anxiety and insomnia.'' *Id.* The Expert also noted that on May 31, 2012, Respondent increased D.B.'s clonazepam prescription ''without any justification.'' *Id.*

With respect to Respondent's treatment plan, the Expert found that it ''was wholly inadequate and, again, consisted only of a checklist of recommendations,'' and that there was no ''evidence that any of the recommendations were either discussed or followed.'' *Id.* The Expert also noted that while Respondent ''recommended 'glucosamine/Chondroitin Sulfate,' and stated that that she will 'refer to PT, neurologist, neurosurgeon, orthopedist, psychiatrist, psychiatrist, addiction specialist as needed[,]' [t]here is no evidence that any of these alternative measures were attempted, [or] that any referrals were made.'' *Id.*

Based on the above, I conclude that Respondent acted outside of the usual course of professional practice and lacked a legitimate medical purpose when she prescribed controlled substances to D.B. Indeed, with respect to D.G., J.A., and D.B., the Expert concluded that Respondent ''provided them with prescriptions for controlled substances in contravention of the standards of care and practice in the State of Florida and with indifference to various indicators or 'red flags' that the patients were engaged in drug abuse and/or diversion.'' *Id.* at 6.

Factor Five—Such Other Conduct Which May Threaten Public Health and Safety

The Government argues that Respondent's acts in providing the UC with two Ibuprofen prescriptions to help him fill his controlled substance prescriptions without suspicion constitute conduct to be considered under Factor Five (such other conduct which may threaten the public health and safety). RFAA, at 19. It contends there is ''a substantial relationship between the conduct and the CSA's purpose of preventing drug abuse and diversion.'' *Id.* (citing *Zvi H. Perper, M.D.,* 77 FR 64131, 64141 (2012) (*quoting Tony T. Bui,* 75 FR 49979, 49988 (2010))).

In *Perper,* the Agency adopted the ALJ's legal conclusion that the act of providing a prescription for a non-

[35] Respondent had seen D.B. three weeks earlier when he reported that he could not fill the oxycodone 30 and Xanax prescriptions written by another PBM doctor.

[36] Of further note, on several progress notes, Respondent circled ''Y'' next to the entry for ''Psych visits/SS Disability past 5 yr[s].'' *See* GE 14, at 60 (Mar. 27 visit), 66 (April 24 visit), 76 (May 31 visit), and 83 (June 28 visit). Yet no such records are in his file.

controlled drug such as Ibuprofen so as not to arouse a pharmacist's suspicion as to the legality of a controlled substance prescription and induce him to fill the prescription constitutes actionable misconduct under Factor Five. *See* 77 FR at 64141. Such conduct is, in essence, a form of subterfuge, and may threaten public health and safety by inducing a pharmacist into believing a controlled substance prescription is lawful rather than questioning its validity and refusing to fill it. *Cf.* 21 U.S.C. 843(a)(3) (''It shall be unlawful for any person knowingly or intentionally . . . to acquire or obtain possession of a controlled substance by misrepresentation, fraud, forgery, deception, or subterfuge.'').

Here, the evidence shows that at the UC's first visit, Respondent told him that she ''was gonna [sic] give you some ibuprofen. Because if you['re] filling in Florida which I encourage you to do so you're on the computer list. Then . . . for two reasons: Number one, the pharmacists usually want a non-prescription drug, a non-controlled substance drug rather . . . and ibuprofen is also good for inflammation.'' GE 7, at 6.

At his second visit, the UC told Respondent that a pharmacist refused to fill the Klonopin prescription she had issued previously. GE 9, at 9. Respondent advised the UC to take the prescription to another pharmacy and told him that it is not doctor-shopping if the pharmacist refused to fill the prescription; she also told the UC that she would ''write that [Klonopin] and I'll write another non-narcotic.'' *Id.* at 10. Respondent subsequently stated she would ''give [the UC] two small prescriptions'' for ibuprofen and ''one narcotic for each pharmacy that [he] might have to go to.'' *Id.* at 16. She added ''I want you to keep the extra ibuprofen so if they won't fill the Klonopin again you have another non-narcotic to use.'' *Id.* at 17.

In advising the UC how to avoid encountering difficulties in filling his prescriptions for controlled substances and in issuing non-narcotic prescriptions to minimize any suspicions by pharmacists, Respondent engaged in ''[s]uch other conduct which may threaten the public health and safety''). *See Perper,* 77 FR at 64141. *Cf. Nelson A. Smith,* 58 FR 65403, 65404 (1993) (holding that using strategies ''to avoid detection . . . such as falsifying patients charts and suggesting that the recipients of . . . illegal prescriptions go to different pharmacies'' is actionable misconduct under Factor Five).

I therefore hold that the Government's evidence with respect to Factors Two, Four, and Five establishes that Registrant ''has committed such acts as would render her registration . . . inconsistent with the public interest.'' 21 U.S.C. 824(a)(4). Because Respondent waived her right to a hearing (or to submit a written statement in lieu of a hearing), there is no evidence in the record to refute the conclusion that her continued registration is ''inconsistent with the public interest.'' *Id.* Accordingly, I will order that Respondent's registration be revoked and that any pending applications be denied.

Order

Pursuant to the authority vested in me by 21 U.S.C. 823(f) and 824(a), as well as 28 CFR 0.100(b), I order that DEA Certificate of Registration No. AS1456361, issued to Marcia L. Sills, M.D., be, and it hereby is, revoked. I further order that any pending application of Marcia L. Sills to renew or modify the above registration, or any pending application of Marcia L. Sills for any other registration, be, and it hereby is, denied. This Order is effective September 5, 2017.

Dated: July 27, 2017.

Chuck Rosenberg,

Acting Administrator.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA–470P]

Proposed Adjustments to the Aggregate Production Quotas for Schedule I and II Controlled Substances and Assessment of Annual Needs for the List I Chemicals Ephedrine, Pseudoephedrine, and Phenylpropanolamine for 2017

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Notice with request for comments.

SUMMARY: The Drug Enforcement Administration (DEA) proposes to adjust the 2017 aggregate production quotas for several controlled substances in schedules I and II of the Controlled Substances Act and assessment of annual needs for the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine.

DATES: Interested persons may file written comments on this notice in accordance with 21 CFR 1303.13(c) and 1315.13(d). Electronic comments must be submitted, and written comments must be postmarked, on or before September 5, 2017. Commenters should be aware that the electronic Federal Docket Management System will not accept comments after 11:59 p.m. Eastern Time on the last day of the comment period.

Based on comments received in response to this notice, the Administrator may hold a public hearing on one or more issues raised. In the event the Administrator decides in his sole discretion to hold such a hearing, the Administrator will publish a notice of any such hearing in the **Federal Register**. After consideration of any comments or objections, or after a hearing, if one is held, the Administrator will publish in the **Federal Register** a final order establishing the 2017 adjusted aggregate production quotas for schedule I and II controlled substances, and an assessment of annual needs for the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine.

ADDRESSES: To ensure proper handling of comments, please reference ''Docket No. DEA–470P'' on all correspondence, including any attachments. The Drug Enforcement Administration encourages that all comments be submitted electronically through the Federal eRulemaking Portal which provides the ability to type short comments directly into the comment field on the Web page or attach a file for lengthier comments. Please go to *http://www.regulations.gov* and follow the online instructions at that site for submitting comments. Upon completion of your submission you will receive a Comment Tracking Number for your comment. Please be aware that submitted comments are not instantaneously available for public view on *Regulations.gov.* If you have received a Comment Tracking Number, your comment has been successfully submitted and there is no need to resubmit the same comment. Paper comments that duplicate electronic submissions are not necessary and are discouraged. Should you wish to mail a paper comment *in lieu* of an electronic comment, it should be sent via regular or express mail to: Drug Enforcement Administration, Attention: DEA Federal Register Representative/DRW, 8701 Morrissette Drive, Springfield, Virginia 22152.

FOR FURTHER INFORMATION CONTACT: Michael J. Lewis, Diversion Control Division, Drug Enforcement Administration; Mailing Address: 8701 Morrissette Drive, Springfield, Virginia 22152, Telephone: (202) 598–6812.

SUPPLEMENTARY INFORMATION:

Posting of Public Comments

Please note that all comments received in response to this docket are considered part of the public record. They will, unless reasonable cause is given, be made available by the Drug Enforcement Administration (DEA) for public inspection online at *http://www.regulations.gov.* Such information includes personal identifying information (such as your name, address, etc.) voluntarily submitted by the commenter.

The Freedom of Information Act (FOIA) applies to all comments received. If you want to submit personal identifying information (such as your name, address, etc.) as part of your comment, but do not want it to be made publicly available, you must include the phrase ''PERSONAL IDENTIFYING INFORMATION'' in the first paragraph of your comment. You must also place all the personal identifying information you do not want made publicly available in the first paragraph of your comment and identify what information you want redacted.

If you want to submit confidential business information as part of your comment, but do not want it to be made publicly available, you must include the phrase ''CONFIDENTIAL BUSINESS INFORMATION'' in the first paragraph of your comment. You must also prominently identify confidential business information to be redacted within the comment.

Comments containing personal identifying information or confidential business information identified and located as directed above will generally be made available in redacted form. If a comment contains so much confidential business information or personal identifying information that it cannot be effectively redacted, all or part of that comment may not be made publicly available. Comments posted to *http://www.regulations.gov* may include any personal identifying information (such as name, address, and phone number) included in the text of your electronic submission that is not identified as directed above as confidential.

An electronic copy of this document is available at *http://www.regulations.gov* for easy reference.

Legal Authority and Background

Section 306 of the Controlled Substances Act (CSA) (21 U.S.C. 826) requires the Attorney General to establish aggregate production quotas for each basic class of controlled substance listed in schedules I and II and for the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine. The Attorney General has delegated this function to the Administrator of the DEA pursuant to 28 CFR 0.100.

The DEA established the 2017 aggregate production quotas for substances in schedules I and II and the assessment of annual needs for the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine on October 5, 2016 (81 FR 69079). That notice stipulated that, in accordance with 21 CFR 1303.13 and 1315.13, all aggregate production quotas and assessments of annual need are subject to adjustment.

Analysis for Proposed Adjusted 2017 Aggregate Production Quotas and Assessment of Annual Needs

The DEA proposes to adjust the established 2017 aggregate production quotas and assessment of annual needs for certain schedule I and II controlled substances, and the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine, to be manufactured in the United States in 2017 to provide for the estimated medical, scientific, research, and industrial needs of the United States, for lawful export requirements, and for the establishment and maintenance of reserve stocks. These quotas do not include imports of controlled substances for use in industrial processes.

In determining the proposed adjustment, the Acting Administrator has taken into account the criteria in accordance with 21 CFR 1303.13 (adjustment of aggregate production quotas for controlled substances) and 21 CFR 1315.13 (adjustment of the assessment of annual needs for ephedrine, pseudoephedrine, and phenylpropanolamine). The DEA determined whether to propose an adjustment of the aggregate production quotas and assessment of annual needs for 2017 by considering: (1) Changes in the demand for that class or chemical, changes in the national rate of net disposal of the class or chemical, and changes in the rate of net disposal of the class or chemical by registrants holding individual manufacturing quotas for the class; (2) whether any increased demand for that class or chemical, the national and/or individual rates of net disposal of that class or chemical are temporary, short term, or long term; (3) whether any increased demand for that class or chemical can be met through existing inventories, increased individual manufacturing quotas, or increased importation, without increasing the aggregate production quota; (4) whether any decreased demand for that class or chemical will result in excessive inventory accumulation by all persons registered to handle that class or chemical; and (5) other factors affecting medical, scientific, research, and industrial needs in the United States and lawful export requirements, as the Acting Administrator finds relevant. These quotas do not include imports of controlled substances for use in industrial processes.

The Acting Administrator also considered updated information obtained from 2016 year-end inventories, 2016 disposition data submitted by quota applicants, estimates of the medical needs of the United States, product development, and other information made available to the DEA after the initial aggregate production quotas and assessment of annual needs had been established. Other factors the Acting Administrator considered in calculating the aggregate production quotas, but not the assessment of annual needs, include product development requirements of both bulk and finished dosage form manufacturers, and other pertinent information. In determining the proposed adjusted 2017 assessment of annual needs, the DEA used the calculation methodology previously described in the 2010 and 2011 established assessment of annual needs (74 FR 60294, Nov. 20, 2009, and 75 FR 79407, Dec. 20, 2010, respectively).

The Acting Administrator, therefore, proposes that the year 2017 aggregate production quotas for the nine temporarily scheduled substances be established, and to adjust the 2017 aggregate production quotas for certain schedule I and II controlled substances and assessment of annual needs for the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine, expressed in grams of anhydrous acid or base, as follows:

Basic class	Established 2017 quotas (g)	Proposed Revised 2017 quotas (g)
Temporarily Scheduled Substances		
4-Fluoroisobutyryl fentanyl	N/A	30.
5F–ADB; 5F–MDMB–PINACA (methyl 2-(1-(5-fluoropentyl)-1H-indazole-3-carboxamido)-3,3-dimethylbutanoate).	N/A	30.
5F–AMB (methyl 2-(1-(5-fluoropentyl)-1*H*-indazole-3-carboxamido)-3-methylbutanoate)	N/A	30.
5F–APINACA; 5F–AKB48 (*N*-(adamantan-1-yl)-1-(5-fluoropentyl)-1*H*-indazole-3-carboxamide)	N/A	30.
ADB–FUBINACA (*N*-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-(4-fluorobenzyl)-1*H*-indazole-3-carboxamide).	N/A	30.
MDMB–CHMICA; MMB–CHMINACA (methyl 2-(1-(cyclohexylmethyl)-1*H*-indole-3-carboxamido)-3,3-dimethylbutanoate).	N/A	30.
MDMB–FUBINACA (methyl 2-(1-(4-fluorobenzyl)-1*H*-indazole-3-carboxamido)-3,3-dimethylbutanoate)	N/A	30.
Furanyl fentanyl	N/A	30.
U–47700	N/A	30.
Schedule I		
1-(1-Phenylcyclohexyl)pyrrolidine	10	no change.
1-(5-Fluoropentyl)-3-(1-naphthoyl)indole (AM2201)	30	no change.
1-(5-Fluoropentyl)-3-(2-iodobenzoyl)indole (AM694)	30	no change.
1-[1-(2-Thienyl)cyclohexyl]piperidine	15	no change.
1-Benzylpiperazine	25	no change.
1-Methyl-4-phenyl-4-propionoxypiperidine	2	no change.
2-(2,5-Dimethoxy-4-ethylphenyl)ethanamine (2C–E)	30	no change.
2-(2,5-Dimethoxy-4-methylphenyl)ethanamine (2C–D)	30	no change.
2-(2,5-Dimethoxy-4-nitro-phenyl)ethanamine (2C–N)	30	no change.
2-(2,5-Dimethoxy-4-n-propylphenyl)ethanamine (2C–P)	30	no change.
2-(2,5-Dimethoxyphenyl)ethanamine (2C–H)	30	no change.
2-(4-Bromo-2,5-dimethoxyphenyl)-N-(2-methoxybenzyl)ethanamine (25B–NBOMe; 2C–B–NBOMe; 25B; Cimbi-36).	25	no change.
2-(4-Chloro-2,5-dimethoxyphenyl)ethanamine (2C–C)	30	no change.
2-(4-Chloro-2,5-dimethoxyphenyl)-N-(2-methoxybenzyl)ethanamine (25C–NBOMe; 2C–C–NBOMe; 25C; Cimbi-82).	25	no change.
2-(4-Iodo-2,5-dimethoxyphenyl)ethanamine (2C–I)	30	no change.
2-(4-Iodo-2,5-dimethoxyphenyl)-N-(2-methoxybenzyl)ethanamine (25I–NBOMe; 2C–I–NBOMe; 25I; Cimbi-5).	5	30.
2,5-Dimethoxy-4-ethylamphetamine (DOET)	25	no change.
2,5-Dimethoxy-4-n-propylthiophenethylamine	25	no change.
2,5-Dimethoxyamphetamine	25	no change.
2-[4-(Ethylthio)-2,5-dimethoxyphenyl]ethanamine (2C–T–2)	30	no change.
2-[4-(Isopropylthio)-2,5-dimethoxyphenyl]ethanamine (2C–T–4)	30	no change.
3,4,5-Trimethoxyamphetamine	25	no change.
3,4-Methylenedioxyamphetamine (MDA)	55	no change.
3,4-Methylenedioxymethamphetamine (MDMA)	50	no change.
3,4-Methylenedioxy-N-ethylamphetamine (MDEA)	40	no change.
3,4-Methylenedioxy-N-methylcathinone (methylone)	40	no change.
3,4-Methylenedioxypyrovalerone (MDPV)	35	no change.
3–FMC; 3-Fluoro-N-methylcathinone	25	no change.
3-Methylfentanyl	2	30.
3-Methylthiofentanyl	2	30.
4-Bromo-2,5-dimethoxyamphetamine (DOB)	25	no change.
4-Bromo-2,5-dimethoxyphenethylamine (2–CB)	25	no change.
4–FMC; Flephedrone	25	no change.
4–MEC; 4-Methyl-N-ethylcathinone	25	no change.
4-Methoxyamphetamine	150	no change.
4-Methyl-2,5-dimethoxyamphetamine (DOM)	25	no change.
4-Methylaminorex	25	no change.
4-Methyl-N-methylcathinone (mephedrone)	45	no change.
4-Methyl-α-pyrrolidinopropiophenone (4-MePPP)	25	no change.
5-(1,1-Dimethylheptyl)-2-[(1R,3S)-3-hydroxycyclohexyl]-phenol	50	no change.
5-(1,1-Dimethyloctyl)-2-[(1R,3S)-3-hydroxycyclohexyl]-phenol (cannabicyclohexanol or CP–47,497 C8-homolog).	40	no change.
5-Fluoro-PB–22; 5F–PB–22	20	no change.
5-Fluoro-UR144, XLR11 ([1-(5-fluoro-pentyl)-1*H*-indol-3-yl](2,2,3,3-tetramethylcyclopropyl)methanone	25	no change.
5-Methoxy-3,4-methylenedioxyamphetamine	25	no change.
5-Methoxy-N,N-diisopropyltryptamine	25	no change.
5-Methoxy-N,N-dimethyltryptamine	25	no change.
AB–CHMINACA	15	30.
AB–FUBINACA	50	no change.
AB–PINACA	15	30.
Acetyl Fentanyl	100	no change.

Basic class	Established 2017 quotas (g)	Proposed Revised 2017 quotas (g)
Acetyl-*alpha*-methylfentanyl	2	30.
Acetyldihydrocodeine	2	30.
Acetylmethadol	2	no change.
ADB–PINACA (*N*-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-pentyl-1*H*-indazole-3-carboxamide)	50	no change.
AH–7921	30	no change.
Allylprodine	2	no change.
Alphacetylmethadol	2	no change.
alpha-Ethyltryptamine	25	no change.
Alphameprodine	2	no change.
Alphamethadol	2	no change.
alpha-Methylfentanyl	2	30.
alpha-Methylthiofentanyl	2	30.
alpha-Methyltryptamine (AMT)	25	no change.
alpha-Pyrrolidinobutiophenone (α-PBP)	25	no change.
alpha-Pyrrolidinopentiophenone (α-PVP)	25	no change.
Aminorex	25	no change.
APINCA, AKB48 (*N*-(1-adamantyl)-1-pentyl-1*H*-indazole-3-carboxamide)	25	no change.
Benzylmorphine	2	30.
Betacetylmethadol	2	no change.
beta-Hydroxy-3-methylfentanyl	2	30.
beta-Hydroxyfentanyl	2	30.
beta-Hydroxythiofentanyl	30	no change.
Betameprodine	2	no change.
Betamethadol	4	no change.
Betaprodine	2	no change.
Bufotenine	3	no change.
Butylone	25	no change.
Butyryl fentanyl	30	no change.
Cathinone	24	no change.
Codeine methylbromide	5	30.
Codeine-N-oxide	305	330
Desomorphine	25	no change.
Diethyltryptamine	25	no change.
Difenoxin	8,750	no change.
Dihydromorphine	1,566,000	no change.
Dimethyltryptamine	35	no change.
Dipipanone	5	no change.
Etorphine	Zero	30.
Fenethylline	5	30.
gamma-Hydroxybutyric acid	56,200,000	no change.
Heroin	25	45.
Hydromorphinol	2	no change.
Hydroxypethidine	2	no change.
Ibogaine	5	30.
JWH–018 and AM678 (1-Pentyl-3-(1-naphthoyl)indole)	35	no change.
JWH–019 (1-Hexyl-3-(1-naphthoyl)indole)	45	no change.
JWH–073 (1-Butyl-3-(1-naphthoyl)indole)	45	no change.
JWH–081 (1-Pentyl-3-[1-(4-methoxynaphthoyl)]indole)	30	no change.
JWH–122 (1-Pentyl-3-(4-methyl-1-naphthoyl)indole)	30	no change.
JWH–200 (1-[2-(4-Morpholinyl)ethyl]-3-(1-naphthoyl)indole)	35	no change.
JWH–203 (1-Pentyl-3-(2-chlorophenylacetyl)indole)	30	no change.
JWH–250 (1-Pentyl-3-(2-methoxyphenylacetyl)indole)	30	no change.
JWH–398 (1-Pentyl-3-(4-chloro-1-naphthoyl)indole)	30	no change.
Lysergic acid diethylamide (LSD)	10	40.
MAB–CHMINACA; ADB–CHMINACA (*N*-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-(cyclohexylmethyl)-1*H*-indazole-3-carboxamide).	Zero	30.
Marihuana	472,000	no change.
Mecloqualone	Zero	30.
Mescaline	25	no change.
Methaqualone	10	60.
Methcathinone	25	no change.
Methyldesorphine	5	no change.
Methyldihydromorphine	2	no change.
Morphine methylbromide	5	no change.
Morphine methylsulfonate	5	no change.
Morphine-N-oxide	350	no change.
N,N-Dimethylamphetamine	25	no change.
Naphyrone	25	no change.
N-Ethyl-1-phenylcyclohexylamine	5	no change.
N-Ethylamphetamine	24	no change.
N-Hydroxy-3,4-methylenedioxyamphetamine	24	no change.

Basic class	Established 2017 quotas (g)	Proposed Revised 2017 quotas (g)
Noracymethadol	2	no change.
Norlevorphanol	52	55.
Normethadone	2	no change.
Normorphine	40	no change.
Para-fluorofentanyl	5	25.
Parahexyl	5	no change.
PB–22; QUPIC	20	no change.
Pentedrone	25	no change.
Pentylone	25	no change.
Phenomorphan	2	no change.
Pholcodine	5	no change.
Psilocybin	30	no change.
Psilocyn	50	no change.
SR–18 and RCS–8 (1-Cyclohexylethyl-3-(2-methoxyphenylacetyl)indole)	45	no change.
SR–19 and RCS–4 (1-Pentyl-3-[(4-methoxy)-benzoyl]indole)	30	no change.
Tetrahydrocannabinols	409,000	no change.
Thiofentanyl	2	25.
THJ–2201 ([1-(5-fluoropentyl)-1H-indazol-3-yl](naphthalen-1-yl)methanone)	15	30.
Tilidine	25	no change.
Trimeperidine	2	no change.
UR–144 (1-pentyl-1H-indol-3-yl)(2,2,3,3-tetramethylcyclopropyl)methanone	25	no change.
Schedule II		
1-Phenylcyclohexylamine	4	no change.
1-Piperidinocyclohexanecarbonitrile	4	no change.
4-Anilino-N-phenethyl-4-piperidine (ANPP)	1,750,000	no change.
Alfentanil	4,200	no change.
Alphaprodine	2	no change.
Amobarbital	20,100	no change.
Amphetamine (for conversion)	12,000,000	no change.
Amphetamine (for sale)	42,400,000	no change.
Carfentanil	10	20.
Cocaine	103,400	no change.
Codeine (for conversion)	40,000,000	no change.
Codeine (for sale)	45,000,000	no change.
Dextropropoxyphene	15	35.
Dihydrocodeine	281,100	422,000.
Dihydroetorphine	2	no change.
Diphenoxylate (for conversion)	15,000	no change.
Diphenoxylate (for sale)	820,000	1,110,000.
Ecgonine	99,000	no change.
Ethylmorphine	2	30.
Etorphine hydrochloride	32	no change.
Fentanyl	1,750,000	no change.
Glutethimide	2	no change.
Hydrocodone (for conversion)	122,000	no change.
Hydrocodone (for sale)	58,410,000	no change.
Hydromorphone	5,140,800	no change.
Isomethadone	4	30.
Levo-alphacetylmethadol (LAAM)	3	5.
Levomethorphan	10	30.
Levorphanol	8,300	12,900.
Lisdexamfetamine	19,000,000	no change.
Meperidine	3,706,000	no change.
Meperidine Intermediate-A	5	no change.
Meperidine Intermediate-B	9	30.
Meperidine Intermediate-C	5	no change.
Metazocine	15	no change.
Methadone (for sale)	23,700,000	no change.
Methadone Intermediate	25,600,000	no change.
Methamphetamine	1,539,100	no change.
[900,000 grams of levo-desoxyephedrine for use in a non-controlled, non-prescription product; 600,000 grams for methamphetamine mostly for conversion to a schedule III product; and 39,100 grams for methamphetamine (for sale)].		
Methylphenidate	73,000,000	no change.
Morphine (for conversion)	27,300,000	no change.
Morphine (for sale)	41,000,000	no change.
Nabilone	19,000	no change.
Noroxymorphone (for conversion)	17,700,000	no change.
Noroxymorphone (for sale)	400,000	no change.

Basic class	Established 2017 quotas (g)	Proposed Revised 2017 quotas (g)
Opium (powder)	90,000	no change.
Opium (tincture)	907,200	600,000.
Oripavine	22,000,000	22,700,000.
Oxycodone (for conversion)	2,610,000	no change.
Oxycodone (for sale)	108,510,000	no change.
Oxymorphone (for conversion)	22,300,000	no change.
Oxymorphone (for sale)	4,200,000	no change.
Pentobarbital	27,500,000	no change.
Phenazocine	5	no change.
Phencyclidine	20	35.
Phenmetrazine	2	25.
Phenylacetone	20	40.
Racemethorphan	2	5.
Racemorphan	2	5.
Remifentanil	3,000	no change.
Secobarbital	172,002	no change.
Sufentanil	4,000	no change.
Tapentadol	21,000,000	no change.
Thebaine	100,000,000	no change.
List I Chemicals		
Ephedrine (for conversion)	50,000	no change.
Ephedrine (for sale)	5,360,000	no change.
Phenylpropanolamine (for conversion)	15,000,000	no change.
Phenylpropanolamine (for sale)	8,500,000	no change.
Pseudoephedrine (for conversion)	40	no change.
Pseudoephedrine (for sale)	200,00,000	no change.

The Acting Administrator further proposes that aggregate production quotas for all other schedule I and II controlled substances included in 21 CFR 1308.11 and 1308.12 remain at zero. In accordance with 21 CFR 1303.13 and 21 CFR 1315.13, upon consideration of the relevant factors, the Acting Administrator may adjust the 2017 aggregate production quotas and assessment of annual needs as needed.

Conclusion

After consideration of any comments or objections, or after a hearing, if one is held, the Acting Administrator will issue and publish in the **Federal Register** a final order establishing any adjustment of 2017 aggregate production quota for each basic class of controlled substances in schedules I and II and established assessment of annual needs for the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine, 21 CFR 1303.13(c) and 1315.13(f).

Dated: July 27, 2017.

Chuck Rosenberg,

Acting Administrator.

[FR Doc. 2017–16440 Filed 8–3–17; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF LABOR

Office of the Secretary

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Claim for Continuance of Compensation

ACTION: Notice of availability; request for comments.

SUMMARY: The Department of Labor (DOL) is submitting the Office of Workers' Compensation Programs (OWCP) sponsored information collection request (ICR) revision titled, ''Claim for Continuance of Compensation,'' to the Office of Management and Budget (OMB) for review and approval for use in accordance with the Paperwork Reduction Act (PRA) of 1995. Public comments on the ICR are invited.

DATES: The OMB will consider all written comments that agency receives on or before September 5, 2017.

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 of charge from the *RegInfo.gov* Web site at *http://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=201703-1240-005* (this link will only become active on the day following publication of this notice) or by contacting Michel Smyth by telephone at 202–693–4129, TTY 202–693–8064, (these are not toll-free numbers) or sending an email to *DOL_PRA_PUBLIC@dol.gov.*

Submit comments about this request by mail or courier to the Office of Information and Regulatory Affairs, Attn: OMB Desk Officer for DOL–OWCP, Office of Management and Budget, Room 10235, 725 17th Street NW., Washington, DC 20503; by Fax: 202–395–5806 (this is not a toll-free number); or by email: *OIRA_submission@omb.eop.gov.* Commenters are encouraged, but not required, to send a courtesy copy of any comments by mail or courier to the U.S. Department of Labor–OASAM, Office of the Chief Information Officer, Attn: Departmental Information Compliance Management Program, Room N1301, 200 Constitution Avenue NW., Washington, DC 20210; or by email: *DOL_PRA_PUBLIC@dol.gov.*

FOR FURTHER INFORMATION CONTACT: Michel Smyth by telephone at 202–693–4129, TTY 202–693–8064, (these are not toll-free numbers) or sending an email to *DOL_PRA_PUBLIC@dol.gov.*

Authority: 44 U.S.C. 3507(a)(1)(D).

SUPPLEMENTARY INFORMATION: This ICR seeks approval under the PRA for revisions to the Claim for Continuance of Compensation (Form CA–12)

information collection. The OWCP uses Form CA–12 to obtain information from eligible survivors receiving death benefits for an extended period of time. This information is necessary to ensure the OWCP pays accurate compensation. This information collection has been classified as a revision, because the Form CA–12 instructions and several questions have been revised and electronic submission into case records is now available.

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. The DOL obtains OMB approval for this information collection under Control Number 1240–0015. The DOL notes that existing information collection requirements submitted to the OMB receive a month-to-month extension while they undergo review. New requirements would only take effect upon OMB approval. For additional substantive information about this ICR, see the related notice published in the **Federal Register** on April 5, 2017 (82 FR 16633).

Interested parties are encouraged to send comments to the OMB, Office of Information and Regulatory Affairs at the address shown in the **ADDRESSES** section within thirty (30) days of publication of this notice in the **Federal Register**. In order to help ensure appropriate consideration, comments should mention OMB Control Number 1240–0015. The OMB 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, including the validity of the methodology and assumptions used;
- Enhance the quality, utility, and clarity of the information to be collected; and
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Agency: DOL–OWCP.

Title of Collection: Claim for Continuance of Compensation.

OMB Control Number: 1240–0015.

Affected Public: Individuals or Households.

Total Estimated Number of Respondents: 3,552.

Total Estimated Number of Responses: 3,552.

Total Estimated Annual Time Burden: 295 hours.

Total Estimated Annual Other Costs Burden: $1,847.

Dated: July 31, 2017.

Michel Smyth,

Departmental Clearance Officer.

[FR Doc. 2017–16423 Filed 8–3–17; 8:45 am]

BILLING CODE 4510–CH–P

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[Notice: (17–056)]

Notice of Information Collection

AGENCY: National Aeronautics and Space Administration (NASA).

ACTION: Notice of information collection.

SUMMARY: The National Aeronautics and Space Administration, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995.

DATES: All comments should be submitted within 30 calendar days from August 4, 2017.

ADDRESSES: Interested persons are invited to submit written comments regarding the proposed information collection to the Office of Information and Regulatory Affairs, Office of Management and Budget, 725 7th Street NW., Washington, DC 20543. Attention: Desk Officer for NASA.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the information collection instrument(s) and instructions should be directed to Frances Teel, NASA PRA Clearance Officer, NASA Headquarters, 300 E Street SW., Mail Code JF000, Washington, DC 20546, (202) 358–2225.

SUPPLEMENTARY INFORMATION:

I. Abstract

The National Aeronautics and Space Administration (NASA) Office of Diversity and Equal Opportunity and the Office of Procurement, in accordance with Title VI of the Civil Rights Act of 1964, Title IX of the Education Amendments of 1972, Section 504 of the Rehabilitation Act of 1973, and the Age Discrimination Act of 1975, requires grant awardees to submit an assurance of non-discrimination (NASA Form 1206) as part of their initial grant application package. The requirement for assurance of nondiscrimination compliance associated with federally assisted programs is long standing, derives from civil rights implementing regulations, and extends to the grant recipient's sub-grantees, contractors, successors, transferees, and assignees. Grant selectees are required to submit compliance information triennially when their award period exceeds 36 consecutive months. This information collection will also be used to enable NASA to conduct post-award civil rights compliance reviews.

II. Method of Collection

Electronic.

III. Data

Title: NASA Assurance of Civil Rights Compliance.

OMB Number: 2700–0148.

Type of Review: Reinstatement without change of an existing information collection.

Affected Public: Business, other for-profit, or not-for-profit.

Estimated Number of Respondents: 800.

Estimated Annual Responses: 250.

Estimated Time per Response: 4 hours.

Estimated Total Annual Burden Hours: 16.6.

Estimated Total Annual Cost: $120.

IV. Request for Comments

Comments are invited on: (1) Whether the proposed collection of information is necessary for the proper performance of the functions of NASA, including whether the information collected has practical utility; (2) the accuracy of NASA's estimate of the burden (including hours and cost) of the proposed collection of information; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including automated collection techniques or the use of other forms of information technology.

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

Frances Teel,

NASA PRA Clearance Officer.

[FR Doc. 2017–16387 Filed 8–3–17; 8:45 am]

BILLING CODE 7510–13–P

NATIONAL SCIENCE FOUNDATION

Proposal Review; Notice of Meetings

In accordance with the Federal Advisory Committee Act (Pub. L. 92–463, as amended), the National Science Foundation (NSF) announces its intent to hold proposal review meetings throughout the year. The purpose of these meetings is to provide advice and recommendations concerning proposals submitted to the NSF for financial support. The agenda for each of these meetings is to review and evaluate proposals as part of the selection process for awards. The review and evaluation may also include assessment of the progress of awarded proposals. These meetings will primarily take place at NSF's current headquarters, 4201 Wilson Blvd., Arlington, Virginia 22230 or NSF's new headquarters, 2415 Eisenhower Avenue, Alexandria, VA 22314.

These meetings will be closed to the public. The proposals being reviewed include information of a proprietary or confidential nature, including technical information; financial data, such as salaries; and personal information concerning individuals associated with the proposals. These matters are exempt under 5 U.S.C. 552b(c), (4) and (6) of the Government in the Sunshine Act. NSF will continue to review the agenda and merits of each meeting for overall compliance of the Federal Advisory Committee Act.

These closed proposal review meetings will not be announced on an individual basis in the **Federal Register**. NSF intends to publish a notice similar to this on a quarterly basis. For an advance listing of the closed proposal review meetings that include the names of the proposal review panel and the time, date, place, and any information on changes, corrections, or cancellations, please visit the NSF Web site: *https://www.nsf.gov/events/advisory.jsp.* This information may also be requested by telephoning, 703–292–8687.

Dated: August 1, 2017.

Crystal Robinson,

Committee Management Officer.

[FR Doc. 2017–16426 Filed 8–3–17; 8:45 am]

BILLING CODE 7555–01–P

NATIONAL SCIENCE FOUNDATION

Final Environmental Impact Statement (FEIS) for the Arecibo Observatory, Arecibo, Puerto Rico

AGENCY: National Science Foundation.

ACTION: Notice of availability.

SUMMARY: The National Science Foundation (NSF) announces the availability of the Final Environmental Impact Statement (FEIS) for Arecibo Observatory. This Final EIS identifies and analyzes the potential consequences of the following alternatives: *Alternative 1,* Collaboration with Interested Parties for Continued Science-focused Operations *(Agency-preferred Alternative); Alternative 2,* Collaboration with Interested Parties for Transition to Education-focused Operations; *Alternative 3,* Mothballing of Facilities; *Alternative 4,* Partial Demolition and Site Restoration; and *Alternative 5,* Complete Demolition and Site Restoration; and the *No Action Alternative,* Continued NSF Investment for Science-focused Operations. It also proposes mitigation measures to minimize the adverse impacts from demolition or operation of the alternatives where such impacts may occur. Consultation under Section 106 of the National Historic Preservation Act (NHPA) is being conducted concurrent to the NEPA process.

DATES: The National Science Foundation will execute a Record of Decision no sooner than 30 days after the date of publication of the Notice of Availability published in the **Federal Register** by the Environmental Protection Agency.

ADDRESSES: The Final EIS is made available for public inspection on-line at *www.nsf.gov/AST.* A Spanish translation of the Executive Summary of the Final EIS is posted.

A copy of the DEIS will be available for review at the following libraries in Puerto Rico:

Biblioteca Electrónica Pública Municipal Nicolás Nadal Barreto, 210 Calle Santiago Iglesias, Arecibo, PR, Phone: (787) 878–1178

Archivo General y Biblioteca Nacional de PR, 500 Avenida Juan Ponce De León, San Juan, PR, Phone: (787) 725–1060 ext. 2001

FOR FURTHER INFORMATION CONTACT: Ms. Elizabeth Pentecost, Re: Arecibo Observatory, 4201 Wilson Blvd., Room 1045, Arlington, VA 22230; *envcomp-AST@nsf.gov;* 703–292–4907.

SUPPLEMENTARY INFORMATION: The Arecibo Observatory is an NSF-owned scientific research and education facility located in Puerto Rico. In 2011, NSF awarded a Cooperative Agreement to SRI International (SRI), which together with Universities Space Research Association (USRA) and Universidad Metropolitana (UMET) formed the Arecibo Management Team to operate and maintain the Arecibo Observatory for the benefit of research communities. The initial 5-year period of performance of the Cooperative Agreement was extended 18 months, to 31 March 2018. Arecibo Observatory enables research in three scientific disciplines: space and atmospheric sciences, radio astronomy, and solar system radar studies; the last of these is largely funded through a research award to USRA from the National Aeronautics and Space Administration. An education and public outreach program complements the Arecibo Observatory scientific program. A key component of the Arecibo Observatory research facility is a 305-meter diameter, fixed, spherical reflector. Arecibo Observatory infrastructure includes instrumentation for radio and radar astronomy and ionospheric physics, office and laboratory buildings, a heavily utilized visitor and education facility, and lodging facilities for visiting scientists.

Through a series of academic community-based and portfolio reviews, NSF identified the need to divest of several facilities from its portfolio in order to retain the balance of capabilities needed to deliver the best performance on the key science of the present decade and beyond. In 2016, NSF completed a feasibility study to inform and define options for the observatory's future disposition that would involve significantly decreasing or eliminating NSF funding of Arecibo. Concurrently, NSF sought viable concepts of operations from the scientific community via a Dear Colleague Letter NSF 16–005 (see *www.nsf.gov/AST*). NSF issued a Notice of Intent to prepare an EIS on May 23, 2016, held scoping meetings on June 7, 2016, and held a 30-day public comment period that closed on June 23, 2016. On September 30, 2016, NSF issued a Dear Colleague Letter NSF 16–144 (see *www.nsf.gov/AST*) to notify the Observatory stakeholder community that NSF intended to issue a follow-up solicitation, requesting the submission of formal proposals involving the continued operation of Arecibo

Observatory to provide additional information for the decision process for the ultimate disposition of Arecibo Observatory. The solicitation (NSF 17–538) was released on January 25, 2017.

The Draft EIS was made available for public review and comment from October 28, 2016, through December 12, 2016. The full Draft EIS was also posted on the NSF, Division of Astronomical Sciences Web site (*www.nsf.gov/AST*) and hard copies were delivered to local libraries. During the review period, the NSF received over 400 comments—the majority of comments were against closing the Arecibo Observatory and suggestions for what resources to include in the EIS. After considering all comments received, the NSF prepared the Final EIS. There are no substantive changes to the range of alternatives considered. *Alternative 1* is identified as the ''Agency-preferred Alternative.''

Dated: August 1, 2017.

Suzanne H. Plimpton,

Reports Clearance Officer, National Science Foundation.

[FR Doc. 2017–16435 Filed 8–3–17; 8:45 am]

BILLING CODE 7555–01–P

NUCLEAR REGULATORY COMMISSION

[NRC–2017–0171]

Evaluating Deviations and Reporting Defects and Noncompliance

AGENCY: Nuclear Regulatory Commission.

ACTION: Draft regulatory guide; request for comment.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is issuing for public comment draft regulatory guide (DG), DG–1291, ''Evaluating Deviations and Reporting Defects and Noncompliance Under 10 CFR part 21.'' This DG describes methods that the NRC staff considers acceptable for complying with the provisions of the regulations.

DATES: Submit comments by October 3, 2017. Comments received after this date will be considered if it is practical to do so, but the NRC is able to ensure consideration only for comments received on or before this date. Although a time limit is given, comments and suggestions in connection with items for inclusion in guides currently being developed or improvements in all published guides are encouraged at any time.

ADDRESSES: You may submit comments by any of the following methods (unless this document describes a different method for submitting comments on a specified subject):

- *Federal Rulemaking Web site:* Go to *http://www.regulations.gov* and search for Docket ID NRC–2017–0171. Address questions about NRC dockets to Carol Gallagher; telephone: 301–415–3463; email: *Carol.Gallagher@nrc.gov.* For technical questions, contact the individuals listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.
- *Mail comments to:* Cindy Bladey, Office of Administration, Mail Stop: TWFN–8–D36M, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.

For additional direction on accessing information and submitting comments, see ''Obtaining Information and Submitting Comments'' in the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: Paul Prescott, Office of New Reactors, telephone: 301–415–6263; email: *Paul.Prescott@nrc.gov,* and Stephen Burton, Office of Nuclear Regulatory Research, telephone: 301–415–7000; email: *Stephen.Burton@nrc.gov.* Both are staff of the U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.

SUPPLEMENTARY INFORMATION:

I. Obtaining Information and Submitting Comments

A. Obtaining Information

Please refer to Docket ID NRC–2017–0171 when contacting the NRC about the availability of information regarding this action. You may obtain publicly-available information related to this action, by any of the following methods:

- *Federal Rulemaking Web site:* Go to *http://www.regulations.gov* and search for Docket ID NRC–2017–0171.
- *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.* The DG is available in ADAMS under Accession No. ML16165A298.
- *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.

B. Submitting Comments

Please include Docket ID NRC–2017–0171 in your comment submission.

The NRC cautions you not to include identifying or contact information that you do not want to be publicly disclosed in your comment submission. The NRC posts all comment submissions at *http://www.regulations.gov* as well as enters the comment submissions into ADAMS. The NRC does not routinely edit comment submissions to remove identifying or contact information.

If you are requesting or aggregating comments from other persons for submission to the NRC, then you should inform those persons not to include identifying or contact information that they do not want to be publicly disclosed in their comment submission. Your request should state that the NRC does not routinely edit comment submissions to remove such information before making the comment submissions available to the public or entering the comment submissions into ADAMS.

II. Additional Information

The NRC is issuing for public comment a draft regulatory guide in the NRC's ''Regulatory Guide'' series. This series was developed to describe and make available to the public information regarding methods that are acceptable to the NRC staff for implementing specific parts of the NRC's regulations, techniques that the staff uses in evaluating specific issues or postulated events, and data that the staff needs in its review of applications for permits and licenses.

The draft regulatory guide, entitled, ''Evaluating Deviations and Reporting Defects and Noncompliance Under 10 CFR part 21,'' is a proposed new guide temporarily identified by its task number, DG–1291. The DG–1291 describes methods that the NRC staff considers acceptable for complying with the provisions of part 21 of title 10 of the *Code of Federal Regulations* (10 CFR), ''Reporting of Defects and Noncompliance.''

The DG–1291 provides licensees and applicants with formal guidance for an acceptable method of evaluating and reporting defects under 10 CFR part 21. This new guidance will aid in minimizing compliance challenges to licensees and vendors that have been identified through inspection activities. Specifically, this DG approves NRC licensees' use of a method of evaluating and reporting defects described in NEI 14–09, ''Guidelines for Implementations of 10 CFR part 21 Reporting of Defects

and Noncompliance,'' Revision 1 (ADAMS Accession No. ML16054A825).

III. Specific Request for Comments

The NRC seeks comments on DG–1291, ''Evaluating Deviations and Reporting Defects and Noncompliance Under 10 CFR part 21,'' and requests feedback from commenters about potential regulatory positions that would: (1) Not approve alternative methods for addressing types and locations of postings required under § 21.6 of the regulations in this part, Section 206 of the Energy Reorganization Act of 1974, and the procedures adopted pursuant to the regulations in part 21; and (2) describe training that should be provided for the implementation of procedures adopted pursuant to the regulations.

1. The Nuclear Energy Institute (NEI) developed guidance on implementing the regulatory requirements in 10 CFR part 21. The guidance is contained in NEI 14–09, ''Guidelines for Implementation of 10 CFR part 21 Reporting of Defects and Noncompliance,'' Revision 1 dated August 2014. The guidance in NEI 14–09 interprets NRC's regulations to allow postings to be hard copies, digital copies, or a combination of both. In addition, links to electronic postings may be identified on ''sites'' commonly frequented by workers during the performance of work subject to 10 CFR part 21.

The staff position regarding electronic versions of the documents required by 10 CFR part 21 was provided in ''NRC Responses to 10 CFR part 21 and Fuel Cycle Facility Questions Received during the Vendor Workshop on New Reactor Construction,'' in December 2008 (ADAMS Accession No. ML092660129). Question 27 asked, ''What are the posting requirements for work at home?'' The NRC staff's response stated, ''Section 21.6 requires that every premise in the U.S. where activities subject to part 21 are conducted, posts current copies of (1) the regulations in part 21; (2) Section 206 of the Energy Reorganization Act of 1974; and (3) company procedures adopted pursuant to the regulations in part 21 must be posted in a conspicuous location. If work subject to part 21 is being done at a residence, then that location constitutes a premise for which the relevant notifications must be posted under § 21.6. If posting of the regulations is not practicable at the residence, then the staff considers access to part 21, Section 206, and the company's applicable part 21 reporting procedure, via the internet by 'work at home' personnel to be adequate.''

The NRC is seeking input regarding the adequacy of alternative posting methods and what additional clarity could be provided in the regulatory guide for addressing alternative types and locations of postings required under § 21.6 for the regulations in this part, Section 206 of the Energy Reorganization Act of 1974, and the procedures adopted pursuant to the regulations in this part regardless of the work location.

2. The guidance in NEI 14–09 states, ''10 CFR part 21 does not establish requirements for training of personnel involved in 10 CFR part 21 activities. However, as a good practice, appropriate familiarization and training in the requirements of 10 CFR part 21 should be provided initially, and as appropriate on an ongoing basis, as necessary. As another good practice, an organization should designate individuals capable of assisting the staff in part 21 evaluation, reporting requirements and training requirements.''

The staff position regarding training of personnel involved in 10 CFR part 21 activities was provided in NUREG–0302, ''Remarks Presented (Questions/Answers Discussed) at Public Regional Meetings to Discuss Regulations (10 CFR part 21) for Reporting of Defects and Noncompliance,'' Revision 1, dated July 1977 (ADAMS Accession No. ML062080399). Question 10 on page 21.61–4 asked, ''Can an organization be cited under part 21 for not conducting training on procedures required by part 21?'' The NRC staff's response stated, ''part 21 does not include a requirement for training.'' However, the NRC's current position is that training of personnel involved in 10 CFR part 21 activities would be covered under 10 CFR 50.120, ''Training and qualification of nuclear power plant personnel.''

The NRC is seeking input regarding the position proposed in DG–1291 which approves NEI 14–09 for use because 10 CFR part 21 has no specific requirements for training and the regulation does not provide guidance requiring training of personnel.

3. Are there topics that are not addressed in the RG that should be addressed? Conversely, are there topics addressed in the RG that need not be addressed?

IV. Backfitting and Issue Finality

This DG approves a method for evaluating and reporting defects under 10 CFR part 21. Issuance of this DG, if finalized, would not constitute backfitting as defined in 10 CFR 50.109 (the Backfit Rule) and would not otherwise be inconsistent with the issue finality provisions in 10 CFR part 52. As discussed in the ''Implementation'' section of this DG, the NRC has no current intention to impose this guide, if finalized, on holders of current operating licenses or combined licenses.

Dated at Rockville, Maryland, this 26th day of July, 2017.

For the Nuclear Regulatory Commission.

Thomas H. Boyce,

Chief, Regulatory Guidance and Generic Issues Branch, Division of Engineering, Office of Nuclear Regulatory Research.

[FR Doc. 2017–16429 Filed 8–3–17; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[NRC–2017–0001]

Sunshine Act Meeting Notice

DATE: Weeks of August 7, 14, 21, 28, September 4, 11, 2017.

PLACE: Commissioners' Conference Room, 11555 Rockville Pike, Rockville, Maryland.

STATUS: Public and Closed.

Week of August 7, 2017

There are no meetings scheduled for the week of August 7, 2017.

Week of August 14, 2017—Tentative

There are no meetings scheduled for the week of August 14, 2017.

Week of August 21, 2017—Tentative

There are no meetings scheduled for the week of August 21, 2017.

Week of August 28, 2017—Tentative

There are no meetings scheduled for the week of August 28, 2017.

Week of September 4, 2017—Tentative

Wednesday, September 6, 2017

1:30 p.m. NRC All Employees Meeting (Public Meeting), Marriott Bethesda North Hotel, 5701 Marinelli Road, Rockville, MD 20852.

Thursday, September 7, 2017

10:00 a.m. Briefing on NRC International Activities (Closed—Ex. 1 & 9).

Week of September 11, 2017—Tentative

There are no meetings scheduled for the week of September 11, 2017.

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The schedule for Commission meetings is subject to change on short notice. For more information or to verify the status of meetings, contact Denise

McGovern at 301–415–0681 or via email at *Denise.McGovern@nrc.gov.*

* * * * *

The NRC Commission Meeting Schedule can be found on the Internet at: *http://www.nrc.gov/public-involve/public-meetings/schedule.html.*

* * * * *

The NRC provides reasonable accommodation to individuals with disabilities where appropriate. If you need a reasonable accommodation to participate in these public meetings, or need this meeting notice or the transcript or other information from the public meetings in another format (*e.g.,* braille, large print), please notify Kimberly Meyer, NRC Disability Program Manager, at 301–287–0739, by videophone at 240–428–3217, or by email at *Kimberly.Meyer-Chambers@nrc.gov.* Determinations on requests for reasonable accommodation will be made on a case-by-case basis.

* * * * *

Members of the public may request to receive this information electronically. If you would like to be added to the distribution, please contact the Nuclear Regulatory Commission, Office of the Secretary, Washington, DC 20555 (301–415–1969), or email *Brenda.Akstulewicz@nrc.gov* or *Patricia.Jimenez@nrc.gov.*

Dated: August 2, 2017.

Denise L. McGovern,

Policy Coordinator, Office of the Secretary.

[FR Doc. 2017–16617 Filed 8–2–17; 4:15 pm]

BILLING CODE 7590–01–P

POSTAL REGULATORY COMMISSION

[Docket Nos. CP2017–231; CP2017–232; CP2017–233]

New Postal Products

AGENCY: Postal Regulatory Commission.

ACTION: Notice.

SUMMARY: The Commission is noticing a recent Postal Service filing for the Commission's consideration concerning negotiated service agreements. This notice informs the public of the filing, invites public comment, and takes other administrative steps.

DATES: *Comments are due:* August 8, 2017.

ADDRESSES: Submit comments electronically via the Commission's Filing Online system at *http://www.prc.gov.* Those who cannot submit comments electronically should contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section by telephone for advice on filing alternatives.

FOR FURTHER INFORMATION CONTACT: David A. Trissell, General Counsel, at 202–789–6820.

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Introduction

The Commission gives notice that the Postal Service filed request(s) for the Commission to consider matters related to negotiated service agreement(s). The request(s) may propose the addition or removal of a negotiated service agreement from the market dominant or the competitive product list, or the modification of an existing product currently appearing on the market dominant or the competitive product list.

Section II identifies the docket number(s) associated with each Postal Service request, the title of each Postal Service request, the request's acceptance date, and the authority cited by the Postal Service for each request. For each request, the Commission appoints an officer of the Commission to represent the interests of the general public in the proceeding, pursuant to 39 U.S.C. 505 (Public Representative). Section II also establishes comment deadline(s) pertaining to each request.

The public portions of the Postal Service's request(s) can be accessed via the Commission's Web site (*http://www.prc.gov*). Non-public portions of the Postal Service's request(s), if any, can be accessed through compliance with the requirements of 39 CFR 3007.40.

The Commission invites comments on whether the Postal Service's request(s) in the captioned docket(s) are consistent with the policies of title 39. For request(s) that the Postal Service states concern market dominant product(s), applicable statutory and regulatory requirements include 39 U.S.C. 3622, 39 U.S.C. 3642, 39 CFR part 3010, and 39 CFR part 3020, subpart B. For request(s) that the Postal Service states concern competitive product(s), applicable statutory and regulatory requirements include 39 U.S.C. 3632, 39 U.S.C. 3633, 39 U.S.C. 3642, 39 CFR part 3015, and 39 CFR part 3020, subpart B. Comment deadline(s) for each request appear in section II.

II. Docketed Proceeding(s)

1. *Docket No(s).:* CP2017–231; *Filing Title:* Notice of the United States Postal Service of Filing a Functionally Equivalent Global Plus 1D Negotiated Service Agreement and Application for Non-Public Treatment of Materials Filed Under Seal; *Filing Acceptance Date:* July 31, 2017; *Filing Authority:* 39 CFR 3015.5; *Public Representative:* Lyudmila Y. Bzhilyanskaya; *Comments Due:* August 8, 2017.

2. *Docket No(s).:* CP2017–232; *Filing Title:* Notice of the United States Postal Service of Filing a Functionally Equivalent Global Plus 1D Negotiated Service Agreement and Application for Non-Public Treatment of Materials Filed Under Seal; *Filing Acceptance Date:* July 31, 2017; *Filing Authority:* 39 CFR 3015.5; *Public Representative:* Jennaca D. Upperman; *Comments Due:* August 8, 2017.

3. *Docket No(s).:* CP2017–233; *Filing Title:* Notice of the United States Postal Service of Filing a Functionally Equivalent Global Plus 1D Negotiated Service Agreement and Application for Non-Public Treatment of Materials Filed Under Seal; *Filing Acceptance Date:* July 31, 2017; *Filing Authority:* 39 CFR 3015.5; *Public Representative:* Jennaca D. Upperman; *Comments Due:* August 8, 2017.

This notice will be published in the **Federal Register**.

Stacy L. Ruble,

Secretary.

[FR Doc. 2017–16467 Filed 8–3–17; 8:45 am]

BILLING CODE 7710–FW–P

POSTAL SERVICE

Temporary Emergency Committee of the Board of Governors; Sunshine Act Meeting; Correction

AGENCY: Postal Service.

ACTION: Notice; correction.

SUMMARY: The Postal Service published a document in the **Federal Register** of August 2, 2017, providing notice of a closed meeting of the Temporary Emergency Committee of the Board of Governors. The document specified an incorrect day of the week for the date of the meeting.

FOR FURTHER INFORMATION CONTACT: Julie S. Moore, (202) 268–4800.

Corrections

In the **Federal Register** of August 2, 2017, in FR Doc. 2017–16301:

1. On page 36007, in the third column, correct the **DATES AND TIMES** caption to read:

DATES AND TIMES: Monday, August 7, 2017, at 9:00 a.m.

2. On page 36008, in the first column, correct the first line to read:

Monday, August 7, 2017, at 9:00 a.m.

Dated: August 2, 2017.

Julie S. Moore,

Secretary.

[FR Doc. 2017–16622 Filed 8–2–17; 4:15 pm]

BILLING CODE 7710–12–P

SECURITIES AND EXCHANGE COMMISSION

Proposed Collection; Comment Request

Upon Written Request, Copies Available From: Securities and Exchange Commission, Office of FOIA Services, 100 F Street NE., Washington, DC 20549–2736.

Extension:

Rule 498, SEC File No. 270–574, OMB Control No. 3235–0648

Notice is hereby given that, pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*) (''Paperwork Reduction Act''), the Securities and Exchange Commission (the ''Commission'') is soliciting comments on the collection of information summarized below. The Commission plans to submit this existing collection of information to the Office of Management and Budget (''OMB'') for extension and approval.

Rule 498 (17 CFR 230.498) under the Securities Act of 1933 (15 U.S.C. 77a *et seq.*) (''Securities Act'') permits open-end management investment companies (''funds'') to satisfy their prospectus delivery obligations under the Securities Act by sending or giving key information directly to investors in the form of a summary prospectus (''Summary Prospectus'') and providing the statutory prospectus on a Web site. Upon an investor's request, funds are also required to send the statutory prospectus to the investor. In addition, under rule 498, a fund that relies on the rule to meet its statutory prospectus delivery obligations must make available, free of charge, the fund's current Summary Prospectus, statutory prospectus, statement of additional information, and most recent annual and semi-annual reports to shareholders at the Web site address specified in the required Summary Prospectus legend.[1] A Summary Prospectus that complies with rule 498 is deemed to be a prospectus that is authorized under Section 10(b) of the Securities Act and Section 24(g) of the Investment Company Act of 1940 (15 U.S.C. 80a–1 *et seq.*).

The purpose of rule 498 is to enable a fund to provide investors with a Summary Prospectus containing key information necessary to evaluate an investment in the fund. Unlike many other federal information collections, which are primarily for the use and benefit of the collecting agency, this information collection is primarily for the use and benefit of investors. The information filed with the Commission also permits the verification of compliance with securities law requirements and assures the public availability and dissemination of the information.

Based on an analysis of fund filings, the Commission estimates that approximately 10,532 portfolios are using a Summary Prospectus. The Commission estimates that the annual hourly burden per portfolio associated with the compilation of the information required on the cover page or the beginning of the Summary Prospectus is 0.5 hours, and estimates that the annual hourly burden per portfolio to comply with the Web site posting requirement is approximately 1 hour, requiring a total of 1.5 hours per portfolio per year.[2] Thus the total annual hour burden associated with these requirements of the rule is approximately 15,798.[3] The Commission estimates that the annual cost burden is approximately $15,900 per portfolio, for a total annual cost burden of approximately $167,458,800.[4]

Estimates of average burden hours are made solely for the purposes of the Paperwork Reduction Act and are not derived from a comprehensive or even a representative survey or study of the costs of Commission rules and forms. Under rule 498, use of the Summary Prospectus is voluntary, but the rule's requirements regarding provision of the statutory prospectus upon investor request are mandatory for funds that elect to send or give a Summary Prospectus in reliance upon rule 498. The information provided under rule 498 will not be kept confidential. 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.

Written comments are invited on: (a) Whether the collections of information are necessary for the proper performance of the functions of the Commission, including whether the information has practical utility; (b) the accuracy of the Commission's estimate of the burdens of the collections of information; (c) ways to enhance the quality, utility, and clarity of the information collected; and (d) ways to minimize the burdens of the collections of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted in writing within 60 days of this publication.

Please direct your written comments to Pamela Dyson, Director/Chief Information Officer, Securities and Exchange Commission, C/O Remi Pavlik-Simon, 100 F Street NE., Washington, DC 20549; or send an email to: *PRA_Mailbox@sec.gov.*

Dated: July 31, 2017.

Eduardo A. Aleman,

Assistant Secretary.

[FR Doc. 2017–16391 Filed 8–3–17; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–81265; File No. SR–NASDAQ–2017–038]

Self-Regulatory Organizations; The NASDAQ Stock Market LLC; Notice of Filing of Amendment No. 1, and Order Granting Accelerated Approval of a Proposed Rule Change, as Modified by Amendments No. 1 and 2, Relating to the First Trust Municipal High Income ETF

July 31, 2017.

I. Introduction

On May 16, 2017, The NASDAQ Stock Market LLC (''Nasdaq'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission''), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'')[1] and Rule 19b–4 thereunder,[2] a proposed rule change relating to the First Trust Municipal High Income ETF (''Fund'') of First Trust Exchange-Traded Fund III (''Trust''), the shares of which have been approved by the Commission for listing and trading under Nasdaq Rule 5735 (''Managed Fund Shares''). The proposed rule change was published for

[1] 17 CFR 270.498(e)(1).

[2] 0.5 hours per portfolio + 1 hour per portfolio = 1.5 hours per portfolio. The Commission believes that funds that have opted to use the Summary Prospectus have already incurred the estimated one-time hour burden to initially comply with rule 498, and therefore the estimated burden hours to initially comply with rule 498 and the associated costs are not included in these estimates.

[3] 1.5 hours per portfolio × 10,532 portfolios = 15,798 hours.

[4] $15,900 per portfolio × 9,082 portfolios = $144,403,800.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

comment in the **Federal Register** on June 2, 2017.[3] On July 10, 2017, the Exchange filed Amendment No. 1 to the proposed rule change.[4] On July 11, 2017, the Commission designated a longer period within which to approve the proposed rule change, disapprove the proposed rule change, or institute proceedings to determine whether to disapprove the proposed rule change.[5] On July 13, 2017, the Exchange filed Amendment No. 2 to the proposed rule change.[6] The Commission has received no comments on the proposal. The Commission is publishing this notice to solicit comments on Amendment No. 1 from interested persons, and is approving the proposed rule change, as modified by Amendments No. 1 and 2, on an accelerated basis.

II. The Exchange's Description of the Proposed Rule Change, as Modified by Amendments No. 1 and 2

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Commission has approved the listing and trading of Shares under Nasdaq Rule 5735, which governs the listing and trading of Managed Fund Shares on the Exchange.[7] However, no Shares are currently listed and traded on the Exchange. The Exchange believes the proposed rule change reflects no significant issues not previously addressed in the Prior Release.

The Fund is an actively-managed exchange-traded fund (''ETF''). The Shares will be offered by the Trust, which was established as a Massachusetts business trust on January 9, 2008. The Trust, which is registered with the Commission as an investment company under the Investment Company Act of 1940 (the ''1940 Act''), has filed a registration statement on Form N–1A (''Registration Statement'') relating to the Fund with the Commission.[8] The Fund is a series of the Trust.

The primary purpose of this proposed rule change is to modify certain representations set forth in the Prior Release. Since the Prior Release, in evaluating its ability to construct a portfolio that would both enable the Fund to pursue its investment objectives effectively and satisfy the representations set forth in the Prior Release, the Adviser determined that, based on certain factors, including regulatory and market developments with portfolio management implications, additional flexibility would be needed to launch and operate the Fund. Additionally, the Adviser took into account that recent increases in interest rates have been accompanied by substantial outflows from mutual funds and ETFs, and that future interest rate swings may spark increased market volatility and trigger potentially dramatic inflows and outflows. To enable the Fund to operate effectively (including, in addition to pursuing its investment objectives, responding to potential market volatility), the Adviser believes that additional portfolio management flexibility is needed and warranted. Additionally, for the reasons discussed in more detail below, the Exchange believes that the proposal is consistent with Section 6(b)(5) of the Act.

As a related matter, the Exchange notes that although the Prior Release included certain representations that were based on the generic listing standards for index-based ETFs, the Exchange's ''generic listing standards'' for actively-managed ETFs (the ''Active ETF Generic Listing Standards'')[9] were recently adopted and, with one exception, the Fund's proposed revised representations would meet or exceed similar requirements for portfolios of fixed income securities set forth in Nasdaq Rule 5735(b)(1)(B) under the Active ETF Generic Listing Standards (''Rule 5735(b)(1)(B)''). In addition, this proposed rule change would make certain changes to the description of the Fund's investments. Further, to provide the Adviser with greater flexibility in hedging interest rate risks associated with the Fund's portfolio investments, this proposed rule change would expand the Fund's ability to invest in derivatives by permitting it to invest in over-the-counter (''OTC'') forward contracts and OTC swaps, subject to a limitation that would be consistent with the limitation on investments in OTC derivatives set forth in Nasdaq Rule 5735(b)(1)(E) under the Active ETF Generic Listing Standards (''Rule 5735(b)(1)(E)'').

Changes to Representations

The Prior Release noted that the Fund would be actively managed and not tied to an index, but that under normal market conditions, on a continuous basis determined at the time of purchase, its portfolio of Municipal Securities (as defined in the Prior Release) would generally meet, as applicable, all except for two of the criteria for non-actively managed, index-based, fixed income ETFs contained in Nasdaq Rule 5705(b)(4)(A),

[3] *See* Securities Exchange Act Release No. 80802 (May 26, 2017), 82 FR 25648 (Jun. 2, 2017) (''Notice'').

[4] In Amendment No. 1, which amended and replaced the proposed rule change in its entirety, the Exchange: (a) modified the requirement that the Fund invest at least 65% of its net assets in Municipal Securities (as defined herein) that are rated below investment grade to at least 50% of its net assets; (b) modified the limitation that the Fund invest up to 35% of its net assets in investment grade Municipal Securities to up to 50% of its net assets; and (c) removed references to the Liquidity Rule. Amendment No. 1 to the proposed rule change is available on the Commission's Web site at: *https://www.sec.gov/comments/sr-nasdaq-2017-038/nasdaq2017038-1841718-155073.pdf.*

[5] *See* Securities Exchange Act Release No. 81123 (Jul. 11, 2017), 82 FR 32737 (Jul. 17, 2017). The Commission designated August 31, 2017, as the date by which the Commission shall either approve or disapprove, or institute proceedings to determine whether to disapprove, the proposed rule change. *See id.*

[6] In Amendment No. 2, which partially amended the proposed rule change, as modified by Amendment No. 1, the Exchange provided the rationale with respect to the modifications to the percentages of investment grade and non-investment grade Municipal Securities in which the Fund may invest. Because Amendment No. 2 makes clarifying changes and does not present unique or novel regulatory issues, it is not subject to notice and comment. Amendment No. 2 is available on the Commission's Web site at: *https://www.sec.gov/comments/sr-nasdaq-2017-038/nasdaq2017038-1851791-155341.pdf. See infra* notes 30–32 (noting where the Exchange provided the rationale with respect to the modifications to the percentages of investment grade and non-investment grade Municipal Securities in Amendment No. 2).

[7] The Commission approved Nasdaq Rule 5735 in Securities Exchange Act Release No. 57962 (June 13, 2008), 73 FR 35175 (June 20, 2008) (SR–NASDAQ–2008–039). The Commission previously approved the listing and trading of the Shares of the Fund. *See* Securities Exchange Act Release No. 78913 (September 23, 2016), 81 FR 69109 (October 5, 2016) (SR–NASDAQ–2016–002) (''Prior Release'').

[8] *See* Post-Effective Amendment No. 27 to Registration Statement on Form N–1A for the Trust, dated August 31, 2015 (File Nos. 333–176976 and 811–22245). The descriptions of the Fund and the Shares contained herein are based, in part, on information in the Registration Statement. Before Shares are publicly offered, the Trust will file a post-effective amendment to its Registration Statement. The changes in this proposed rule change will not be implemented for the Fund until the post-effective amendment to the Registration Statement becomes effective. First Trust Advisors L.P. (the ''Adviser'') represents that the Adviser will not implement the changes described herein until the instant proposed rule change is operative.

[9] *See* Securities Exchange Act Release No. 78918 (September 23, 2016), 81 FR 67033 (September 29, 2016).

as described therein. More specifically, the Prior Release stated that, under normal market conditions, the Fund's portfolio of Municipal Securities would meet the requirements of: (i) Nasdaq Rule 5705(b)(4)(A)(i) (requiring that the index or portfolio consist of ''Fixed Income Securities''); (ii) Nasdaq Rule 5705(b)(4)(A)(iv) (requiring that no component fixed income security (excluding Treasury securities) represent more than 30% of the weight of the index or portfolio, and that the five highest weighted component fixed income securities do not, in the aggregate, account for more than 65% of the weight of the index or portfolio); and (iii) Nasdaq Rule 5705(b)(4)(A)(v) (requiring that an underlying index or portfolio (excluding one consisting entirely of exempted securities) include securities from a minimum of 13 non-affiliated issuers) (collectively, the ''Rule 5705-Related Representations'').

Additionally, the Prior Release noted that Nasdaq Rule 5705(b)(4)(A)(iii) (relating to convertible securities) was inapplicable to the Fund's portfolio of Municipal Securities. Further, the Prior Release provided that the Fund's portfolio of Municipal Securities may not satisfy 5705(b)(4)(A)(vi) (requiring that component securities that in the aggregate account for at least 90% of the weight of the index or portfolio be either exempted securities or from a specified type of issuer) and that it would not generally satisfy Rule 5705(b)(4)(A)(ii) (requiring that components that in the aggregate account for at least 75% of the weight of the index or portfolio have a minimum original principal amount outstanding of $100 million or more). However, the Prior Release stated that under normal market conditions, at least 40% (based on dollar amount invested) of the Municipal Securities in which the Fund invested would be issued by issuers with total outstanding debt issuances that, in the aggregate, have a minimum amount of municipal debt outstanding at the time of purchase of $75 million or more (the ''40/75 Representation'').[10]

In addition to the Rule 5705-Related Representations and the 40/75 Representation, the Prior Release provided that under normal market conditions, except for the initial invest-up period and periods of high cash inflows or outflows,[11] the Fund's investments in Municipal Securities would provide exposure (based on dollar amount invested) to (a) at least 10 different industries (with no more than 25% of the value of the Fund's net assets comprised of Municipal Securities that provide exposure to any single industry) and (b) at least 15 different states (with no more than 30% of the value of the Fund's net assets comprised of Municipal Securities that provide exposure to any single state) (collectively, the ''Industry/State Representations''). Additionally, the Prior Release stated that under normal market conditions, except for the initial invest-up period and periods of high cash inflows or outflows, (a) with respect to 75% of the Fund's net assets, the Fund's exposure to any single borrower (based on dollar amount invested) would not exceed 3% of the value of the Fund's net assets and (b) with respect to 15% of the Fund's net assets, the Fund's exposure to any single borrower (based on dollar amount invested) would not exceed 5% of the value of the Fund's net assets (collectively, the ''Borrower Exposure Representations'').

The Prior Release also provided that under normal market conditions, except for the initial invest-up period and periods of high cash inflows or outflows, (a) with respect to the Municipal Securities in which the Fund invested that were rated investment grade by each nationally recognized statistical rating organization (''NRSRO'') rating such securities, at the time of purchase, the applicable borrower would be obligated to pay debt service on issues of municipal obligations that have an aggregate principal amount outstanding of $100 million or more and (b) with respect to all other Municipal Securities in which the Fund invested (referred to as ''Clause B Munis''), at the time of purchase of a Clause B Muni, the borrowers of all Clause B Munis held by the Fund, in the aggregate, would have a weighted average of principal municipal debt outstanding of $50 million or more (collectively, the ''Borrower Debt Representations'' and, together with the Borrower Exposure Representations, the Industry/State Representations, the 40/75 Representation and the Rule 5705-Related Representations, the ''Prior Representations'').

As indicated above, the Adviser has reconsidered the Prior Representations and concluded that additional flexibility will be needed to launch and operate the Fund. As a result, in this proposed rule change, the Exchange is proposing that, going forward: (a) The Prior Representations, except for the Industry/State Representations, would be deleted and (b) the representations included in the next two paragraphs (referred to as the ''New Representations'') would be added. Further, the Exchange notes that the New Representations have been designed to correspond to the requirements of Rule 5735(b)(1)(B), as these are more readily adapted to the Fund (as an actively-managed ETF) than the generic listing standards for index-based ETFs upon which the Rule 5705-Related Representations were based.

Although as described below, certain of the New Representations would meet or exceed similar requirements set forth in Rule 5735(b)(1)(B), it is not anticipated that the Fund would meet the requirement that components that in the aggregate account for at least 75% of the fixed income weight of the portfolio each have a minimum original principal

[10] As noted in the Prior Release, the Commission has previously issued orders approving proposed rule changes relating to the listing and trading under NYSE Arca Equities Rule 5.2(j)(3), Commentary .02 (which governs the listing and trading of fixed-income index ETFs on NYSE Arca, Inc.) to various ETFs that track indexes comprised of municipal securities (including high-yield municipal index ETFs) that did not meet the analogous requirement included in Commentary .02(a)(2) to NYSE Arca Equities Rule 5.2(j)(3), but demonstrated that the portfolio of municipal securities in which the ETFs would invest would be sufficiently liquid (including Securities Exchange Act Release Nos. 75376 (July 7, 2015), 80 FR 40113 (July 13, 2015) (SR–NYSEArca–2015–18) (order approving listing and trading of Vanguard Tax-Exempt Bond Index Fund); 71232 (January 3, 2014), 79 FR 1662 (January 9, 2014) (SR–NYSEArca–2013–118) (order approving listing and trading of Market Vectors Short High-Yield Municipal Index ETF); and 63881 (February 9, 2011), 76 FR 9065 (February 16, 2011) (SR–NYSEArca-2010–120) (order approving listing and trading of SPDR Nuveen S&P High Yield Municipal Bond ETF)). *See also* Securities Exchange Act Release Nos. 67985 (October 4, 2012), 77 FR 61804 (October 11, 2012) (SR–NYSEArca–2012–92) (order approving listing and trading of iShares 2018 S&P AMT-Free Municipal Series and iShares 2019 S&P AMT-Free Municipal Series); 72464 (June 25, 2014), 79 FR 37373 (July 1, 2014) (SR–NYSEArca–2014–45) (order approving continued listing and trading of PowerShares Insured California Municipal Bond Portfolio, PowerShares Insured National Municipal Bond Portfolio and PowerShares Insured New York Municipal Bond Portfolio); 72523 (July 2, 2014), 79 FR 39016 (July 9, 2014) (SR–NYSEArca–2014–37) (order approving listing and trading of iShares 2020 S&P AMT-Free Municipal Series); 75468 (July 16, 2015), 80 FR 43500 (July 22, 2015) (SR–NYSEArca–2015–25) (order approving listing and trading of iShares iBonds Dec 2021 AMT-Free Muni Bond ETF and iShares iBonds Dec 2022 AMT-Free Muni Bond ETF); 78329 (July 14, 2016), 81 FR 47217 (July 20, 2016) (SR–BatsBZX–2016–01) (order approving listing and trading of VanEck Vectors AMT-Free 6–8 Year Municipal Index ETF, VanEck Vectors AMT-Free 8–12 Year Municipal Index ETF, and VanEck Vectors AMT-Free 12–17 Year Municipal Index ETF); and 79885 (January 26, 2017), 82 FR 8963 (February 1, 2017) (SR–NYSEArca–2016–100) (order approving listing and trading of Direxion Daily Municipal Bond Taxable Bear 1X Fund).

[11] As described in the Prior Release, the term ''initial invest-up period'' means the six-week period following the commencement of trading of Shares on the Exchange and the term ''periods of high cash inflows or outflows'' means rolling periods of seven calendar days during which inflows or outflows of cash, in the aggregate, exceed 10% of the Fund's net assets as of the opening of business on the first day of such periods.

amount outstanding of $100 million or more (the ''Generic 100 Requirement'').[12] In general terms, the Fund would operate as an actively-managed ETF that normally invests in a portfolio of Municipal Securities (as defined in the Prior Release, with the modification described below). The Adviser notes that debt issuance sizes for municipal obligations are generally smaller than for corporate obligations.[13] Furthermore, as a general matter, municipal borrowers in certain industries in which the Fund currently intends to invest significantly [14] tend to have less outstanding debt than municipal borrowers in other municipal industries. Therefore, under normal market conditions, except for the initial invest-up period and periods of high cash inflows or outflows,[15] at least 40% (based on dollar amount invested) of the Municipal Securities in which the Fund invests [16] would be issued by issuers with total outstanding debt issuances that, in the aggregate, have a minimum amount of municipal debt outstanding at the time of purchase of $50 million or more (the ''40/50 Representation''). Based on its expertise and understanding of the municipal securities market and the manner in which municipal securities generally trade, the Adviser believes that, notwithstanding both the previous more stringent 40/75 Representation and the Generic 100 Requirement, the 40/50 Representation is appropriate in light of the Fund's investment objectives and the manner in which the Fund intends to pursue them.[17] Given the nature of the municipal securities market and the manner in which municipal securities generally trade, the expected availability of Municipal Securities that would satisfy the Fund's investment parameters, and the debt issuance profiles of the corresponding issuers and borrowers, the 40/50 Representation should both provide the Fund with flexibility to construct its portfolio and, when combined with the Industry/State Representations and the other New Representations included in this filing (including certain representations set forth below pertaining to fixed income securities weightings and number of non-affiliated issuers that are based on, but more stringent than, as applicable, the requirements set forth in Rule 5735(b)(1)(B)), should support the potential for diversity and liquidity, thereby mitigating the Commission's concerns about manipulation.[18]

Under normal market conditions, except for the initial invest-up period and periods of high cash inflows or outflows,[19] no component fixed income security (excluding the U.S. government securities described under the heading ''Other Investments'' in the Prior Release) would represent more than 15% of the Fund's net assets, and the five most heavily weighted component fixed income securities in the Fund's portfolio (excluding U.S. government securities) would not, in the aggregate, account for more than 25% of the Fund's net assets.[20] Further, under normal market conditions, except for the initial invest-up period and periods of high cash inflows or outflows,[21] the Fund's portfolio of Municipal Securities would include securities from a minimum of 30 non-affiliated issuers.[22] Moreover, under normal market conditions, except for the initial invest-up period and periods of high cash inflows or outflows,[23] component securities that in the aggregate account for at least 90% of the weight of the Fund's portfolio of Municipal Securities would be exempted securities as defined in Section 3(a)(12) of the Act (the ''Exempted Securities Representation'').[24] Additionally, to the

[12] *See* Nasdaq Rule 5735(b)(1)(B)(i).

[13] As indicated above in note 10, various ETFs seeking to track indexes comprised of municipal securities have previously sought and obtained approval by the Commission of proposed rule changes because they would not meet the requirement under the applicable generic listing standards that is similar to the Generic 100 Requirement.

[14] These industries include charter schools, senior living facilities (*i.e.,* continuing care retirement communities (''CCRCs'')) and special tax districts, among others. As noted in the Prior Release, in the case of a municipal conduit financing (in general terms, the issuance of municipal securities by an issuer to finance a project to be used primarily by a third party (the ''conduit borrower'')), the ''borrower'' is the conduit borrower (*i.e.,* the party on which a bondholder must rely for repayment) and in the case of other municipal financings, the ''borrower'' is the issuer of the municipal securities.

[15] *See* note 11 regarding the meaning of the terms ''initial invest-up period'' and ''periods of high cash inflows or outflows.''

[16] For the avoidance of doubt, in the case of Municipal Securities that are issued by entities whose underlying assets are municipal bonds (''Municipal Entities''), the underlying municipal bonds would be taken into account.

[17] The Adviser notes that individual issues of municipal securities represented by CUSIPs (*i.e.,* the specific identifying numbers for securities) may be placed into categories according to common characteristics (such as rating, geographical region, purpose, and maturity). Municipal securities that share similar characteristics generally tend to trade similarly to one another; therefore, within these categories, issues may be considered somewhat fungible from a portfolio management perspective, allowing one CUSIP to be represented by another that shares similar characteristics for purposes of developing an investment strategy. Moreover, when municipal securities are close substitutes for one another, pricing vendors may be able to use executed trade information from similar municipal securities as pricing inputs for an individual security. This can make individual securities more liquid because valuations for a single security are generally better estimators of actual trading prices when they are informed by trades in a large group of closely related securities.

[18] The Exchange notes that, in addition to approving the Fund in the Prior Release, the Commission has also approved for listing and trading shares of other actively-managed ETFs that principally hold municipal securities. *See, e.g.,* Securities Exchange Act Release Nos. 60981 (November 10, 2009), 74 FR 59594 (November 18, 2009) (SR–NYSEArca–2009–79) (order approving listing and trading of PIMCO Short Term Municipal Bond Strategy Fund and PIMCO Intermediate Municipal Bond Strategy Fund); 71617 (February 26, 2014), 79 FR 12257 (March 4, 2014) (SR–NYSEArca–2013–135) (order approving listing and trading of db–X Managed Municipal Bond Fund); 71913 (April 9, 2014), 79 FR 21333 (April 15, 2014) (SR–NASDAQ–2014–019) (order approving listing and trading of First Trust Managed Municipal ETF); and 79293 (November 10, 2016), 81 FR 81189 (November 17, 2016) (SR–NYSEArca–2016–107) (order approving listing and trading of Cumberland Municipal Bond ETF).

[19] *See* note 11 regarding the meaning of the terms ''initial invest-up period'' and ''periods of high cash inflows or outflows.''

[20] *See* the Active ETF Generic Listing Standards requirement set forth in Nasdaq Rule 5735(b)(1)(B)(ii), which provides that no component fixed income security (excluding U.S. Treasury securities and government-sponsored entity (''GSE'') securities) may represent more than *30%* of the fixed income weight of the portfolio, and that the five most heavily weighted component fixed income securities in the portfolio (excluding U.S. Treasury securities and GSE securities) may not in the aggregate account for more than *65%* of the fixed income weight of the portfolio. For the avoidance of doubt, in the case of Municipal Securities that are issued by Municipal Entities, the underlying municipal bonds would be taken into account.

[21] *See* note 11 regarding the meaning of the terms ''initial invest-up period'' and ''periods of high cash inflows or outflows.''

[22] For the avoidance of doubt, in the case of Municipal Securities that are issued by Municipal Entities, the underlying municipal bonds would be taken into account. Additionally, for purposes of this restriction, each state and each separate political subdivision, agency, authority, or instrumentality of such state, each multi-state agency or authority, and each guarantor, if any, would be treated as separate, non-affiliated issuers of Municipal Securities. The Active ETF Generic Listing Standards requirement set forth in Nasdaq Rule 5735(b)(1)(B)(iii) provides that generally, an underlying portfolio (excluding exempted securities) that includes fixed income securities must include a minimum of 13 non-affiliated issuers. Although not required, if the Fund's portfolio of Municipal Securities is comprised entirely of securities that meet the definition of ''municipal securities'' set forth in Section 3(a)(29) of the Act, then such portfolio would also be comprised entirely of ''exempted securities'' as defined in Section 3(a)(12) of the Act and, therefore, the requirements of Rule 5735(b)(1)(B)(iii) would not pertain to such portfolio; *see* the Exempted Securities Representation below (which refers to *90%* of the weight of the Fund's portfolio of Municipal Securities).

[23] *See* note 11 regarding the meaning of the terms ''initial invest-up period'' and ''periods of high cash inflows or outflows.''

[24] *See* the Active ETF Generic Listing Standards requirement set forth in Nasdaq Rule 5735(b)(1)(B)(iv)(d). For the avoidance of doubt, in the case of Municipal Securities that are issued by Municipal Entities, the underlying municipal bonds would be taken into account.

extent the Fund invests in Municipal Securities that are mortgage-backed or asset-backed securities, such investments would not account, in the aggregate, for more than 20% of the weight of the fixed income portion of the Fund's portfolio.[25]

The New Representations differ from the Prior Representations and do not, in certain respects, comply with Rule 5735(b)(1)(B) (particularly with respect to the Generic 100 Requirement). However, taking into account the nature of the municipal securities market and the manner in which municipal securities generally trade, in light of the requirements that the New Representations and the Industry/State Representations would impose (*e.g.,* concerning municipal debt outstanding, fixed income securities weightings, issuer diversification, the nature of the securities in which the Fund would invest (including representations relating to exempted securities and mortgage-backed and asset-backed securities), and exposure to industries and states), they should provide support regarding the anticipated diversity and liquidity of the Fund's Municipal Securities portfolio and should mitigate the risks associated with manipulation, while also providing the Adviser with the necessary flexibility to operate the Fund as intended.

Changes to Description of Certain Fund Investments

The Prior Release stated that under normal market conditions, the Fund would seek to achieve its investment objectives by investing at least 80% of its net assets (including investment borrowings) in municipal debt securities that pay interest that is exempt from regular federal income taxes which are ''exempted securities'' under Section 3(a)(12) of the Act (collectively, ''Municipal Securities''). In light of the Exempted Securities Representation, going forward, the Exchange proposes to revise the foregoing by deleting the phrase ''which are 'exempted securities' under Section 3(a)(12) of the Act.'' In addition, the Prior Release stated that the Fund ''may invest up to 20% of its net assets in short-term debt instruments . . . , taxable municipal securities or tax-exempt municipal securities that are not exempted securities under Section 3(a)(12) under the Act, or it may hold cash.'' Going forward, the Exchange proposes to revise the foregoing by replacing the phrase ''taxable municipal securities or tax-exempt municipal securities that are not exempted securities under Section 3(a)(12) under the Act,'' with the phrase ''and taxable municipal securities and other municipal securities that are not Municipal Securities,''.

Additionally, the Prior Release stated that under normal market conditions, the Fund would invest at least 65% of its net assets in Municipal Securities that are, at the time of investment, rated below investment grade (*i.e.,* not rated Baa3/BBB− or above) by at least one NRSRO rating such securities (or Municipal Securities that are unrated and determined by the Adviser to be of comparable quality) (the ''Below Investment Grade Requirement''). The Prior Release also provided that the Fund could invest up to 35% of its net assets in ''investment grade'' Municipal Securities (meaning Municipal Securities that are, at the time of investment, rated investment grade (*i.e.,* rated Baa3/BBB− or above) by each NRSRO rating such securities (or Municipal Securities that are unrated and determined by the Adviser to be of comparable quality)) (the ''Investment Grade Limitation''). Going forward, the Exchange proposes to modify the Below Investment Grade Requirement by replacing the phrase ''Under normal market conditions, the Fund will invest at least 65% of its net assets'' with the following: ''Under normal market conditions, except for the initial invest-up period and periods of high cash inflows or outflows, the Fund will invest at least 50% of its net assets''.[26] Further, the Exchange proposes to modify the Investment Grade Limitation by replacing the phrase ''The Fund may invest up to 35% of its net assets'' with the following: ''Under normal market conditions, except for the initial invest-up period and periods of high cash inflows or outflows, the Fund may not invest more than 50% of its net assets''.[27]

Changes To Expand Permitted Derivatives Investments

As described in the Prior Release, the Fund may (i) invest in exchange-listed options on U.S. Treasury securities, exchange-listed options on U.S. Treasury futures contracts, and exchange-listed U.S. Treasury futures contracts (collectively, the ''Listed Derivatives'') and (ii) acquire short positions in the Listed Derivatives. No changes are being proposed with respect to the Fund's investments in the Listed Derivatives. Going forward, however, the Exchange proposes that the Fund's ability to invest in derivatives would be expanded to permit it to also invest in OTC forward contracts and OTC swaps (collectively, the ''OTC Derivatives'') to hedge interest rate risks associated with the Fund's portfolio investments.

On both an initial and continuing basis, no more than 20% of the assets in the Fund's portfolio would be invested in the OTC Derivatives and, for purposes of calculating this limitation, the Fund's investment in the OTC Derivatives would be calculated as the aggregate gross notional value of the OTC Derivatives.[28] The Fund would only enter into transactions in the OTC Derivatives with counterparties that the Adviser reasonably believes are capable of performing under the applicable contract or agreement.[29] The Fund's investments in both Listed Derivatives and OTC Derivatives would be consistent with the Fund's investment objectives and the 1940 Act and would not be used to seek to achieve a multiple or inverse multiple of an index.

The OTC Derivatives would typically be valued using information provided by a Pricing Service (as defined in the Prior Release). Pricing information for the OTC Derivatives would be available from major broker-dealer firms and/or

[25] *See* the Active ETF Generic Listing Standards requirement set forth in Nasdaq Rule 5735(b)(1)(B)(v).

[26] *See* note 11 regarding the meaning of the terms ''initial invest-up period'' and ''periods of high cash inflows or outflows.'' In addition, to conform to the change to the Below Investment Grade Requirement, the Exchange proposes that, going forward, the phrase ''65% investment requirement'' be replaced with ''50% investment requirement'' in the following statement included in the Prior Release: ''The Municipal Securities in which the Fund will invest to satisfy this 65% investment requirement may include Municipal Securities that are currently in default and not expected to pay the current coupon (''Distressed Municipal Securities'').''

[27] *See* note 11 regarding the meaning of the terms ''initial invest-up period'' and ''periods of high cash inflows or outflows.'' In addition, to conform to the change to the Investment Grade Limitation, the Exchange proposes that, going forward, the phrase ''35% investment limitation'' be replaced with ''50% investment limitation'' in the following statement included in the Prior Release: ''If, subsequent to purchase by the Fund, a Municipal Security held by the Fund experiences an improvement in credit quality and becomes investment grade, the Fund may continue to hold the Municipal Security and it will not cause the Fund to violate the 35% investment limitation; however, the Municipal Security will be taken into account for purposes of determining whether purchases of additional Municipal Securities will cause the Fund to violate such limitation.''

[28] This limitation is consistent with the limitation set forth in Rule 5735(b)(1)(E).

[29] The Fund would seek, where possible, to use counterparties, as applicable, whose financial status is such that the risk of default is reduced; however, the risk of losses resulting from default is still possible. The Adviser would evaluate the creditworthiness of counterparties on an ongoing basis. In addition to information provided by credit agencies, the Adviser's analysis would evaluate each approved counterparty using various methods of analysis and may consider the Adviser's past experience with the counterparty, its known disciplinary history and its share of market participation.

major market data vendors and/or Pricing Services (as defined in the Prior Release).

The Adviser represents that there would be no change to the Fund's investment objectives. Except as provided herein, all other facts presented and representations made in the Prior Release would remain unchanged. The Fund and the Shares would comply with all initial and continued listing requirements under Nasdaq Rule 5735.

2. Statutory Basis

Nasdaq 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. Except as provided herein, all other facts presented and representations made in the Prior Release would remain unchanged. The Fund would comply with all the initial and continued listing requirements under Nasdaq Rule 5735.

The Exchange believes that the proposed rule change is designed to prevent fraudulent and manipulative acts and practices in that the Shares would be listed and traded on the Exchange pursuant to the initial and continued listing criteria in Nasdaq Rule 5735 and, except as provided herein, all other facts presented and representations made in the Prior Release would remain unchanged. The Exchange notes that Shares have not yet been listed on the Exchange. Consistent with the Prior Release, the Exchange represents that trading in the Shares would be subject to the existing trading surveillances, administered by both Nasdaq and also the Financial Industry Regulatory Authority (''FINRA''), on behalf of the Exchange, which are designed to detect violations of Exchange rules and applicable federal securities laws.

The proposed rule change is designed to promote just and equitable principles of trade and to protect investors and the public interest in that the Adviser represents that taking into account the nature of the municipal securities market and the manner in which municipal securities generally trade, in light of the requirements that the New Representations, the Industry/State Representations, the modified Below Investment Grade Requirement and the modified Investment Grade Limitation would impose (*e.g.,* concerning municipal debt outstanding, fixed income securities weightings, issuer diversification, the nature of the securities in which the Fund would invest (including representations relating to exempted securities and mortgage-backed and asset-backed securities), exposure to industries and states, and investments in below investment grade Municipal Securities), they should provide support regarding the anticipated diversity and liquidity of the Fund's Municipal Securities portfolio and should mitigate the risks associated with manipulation, while also providing the Adviser with the necessary flexibility to operate the Fund as intended.[30]

With one exception, the New Representations would meet or exceed similar requirements for portfolios of fixed income securities set forth in Rule 5735(b)(1)(B). In this regard, it is not anticipated that the Fund would meet the Generic 100 Requirement. Based on its expertise and understanding of the municipal securities market and the manner in which municipal securities generally trade, the Adviser believes that, notwithstanding both the previous more stringent 40/75 Representation and the Generic 100 Requirement, the 40/50 Representation is appropriate in light of the Fund's investment objectives and the manner in which the Fund intends to pursue them. Further, given the nature of the municipal securities market and the manner in which municipal securities generally trade, the expected availability of Municipal Securities that would satisfy the Fund's investment parameters, and the debt issuance profiles of the corresponding issuers and borrowers, the 40/50 Representation should both provide the Fund with flexibility to construct its portfolio and, when combined with the Industry/State Representations, the other New Representations, the modified Below Investment Grade Requirement and the modified Investment Grade Limitation, should support the potential for diversity and liquidity, thereby mitigating the Commission's concerns about manipulation.[31]

In connection with the proposal to modify the Below Investment Grade Requirement and the Investment Grade Limitation, the Exchange notes that the Fund's ability to invest in investment grade Municipal Securities would be expanded. Accordingly, Nasdaq believes that this is consistent with the Act because the liquidity profile of the Fund's potential pool of Municipal Securities is expected to increase, which should lessen manipulation concerns.[32]

Further, in connection with the proposal to permit the Fund to invest in the OTC Derivatives, the Exchange notes that the ability to invest in the OTC Derivatives would provide the Adviser with additional flexibility in hedging interest rate risks associated with the Fund's portfolio investments and would be subject to a limitation that is consistent with the limitation set forth in Rule 5735(b)(1)(E). Additionally, the Fund would only enter into transactions in the OTC Derivatives with counterparties that the Adviser reasonably believes are capable of performing under the applicable contract or agreement.

In addition, a large amount of information would be publicly available regarding the Fund and the Shares, thereby promoting market transparency. Moreover, the Intraday Indicative Value (as described in the Prior Release), available on the NASDAQ OMX Information LLC proprietary index data service, would be widely disseminated by one or more major market data vendors and broadly displayed at least every 15 seconds during the Regular Market Session. On each business day, before commencement of trading in Shares in the Regular Market Session on the Exchange, the Fund would disclose on its Web site the Disclosed Portfolio that will form the basis for the Fund's calculation of NAV at the end of the business day.

The proposed rule change is designed to perfect the mechanism of a free and open market and, in general, to protect investors and the public interest. The Exchange notes that the Fund does not yet have publicly offered Shares and does not yet have Shares listed and traded on the Exchange. Before Shares are publicly offered, the Trust will file a post-effective amendment to its Registration Statement. The Shares will not be publicly offered until the post-effective amendment to the Registration Statement becomes effective.

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 impose any burden on competition that is not necessary or appropriate in furtherance

[30] *See* Amendment No. 2, *supra* note 6.

[31] *See id.*

[32] *See id.*

of the purposes of the Act. The Exchange believes that the proposed rule change would provide the Adviser with the flexibility needed to proceed with launching the Fund, accommodating the listing and trading of Managed Fund Shares for an additional actively-managed exchange-traded product, thereby enhancing competition among market participants, to the benefit of investors and the marketplace.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

III. Discussion and Commission Findings

After careful review, the Commission finds that the Exchange's proposal is consistent with the requirements of Section 6 of the Act [33] and the rules and regulations thereunder applicable to a national securities exchange.[34] In particular, the Commission finds that the proposed rule change is consistent with Section 6(b)(5) of the Act,[35] which requires, among other things, that the Exchange's rules be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest.

As described above, the Exchange proposes to: (a) Delete all of the Prior Representations (including the 40/75 Representation), except for the Industry/State Representations; and (b) apply the New Representations. According to the Exchange, the Fund's proposed New Representations would meet the requirements of Nasdaq Rule 5735(b)(1)(B), with the exception of the Generic 100 Requirement. In lieu of the Generic 100 Requirement, the Exchange proposes to apply New Representations, which include the 40/50 Representation. Specifically, the 40/50 Representation requires that, under normal market conditions and except for the initial invest-up period and periods of high cash inflows or outflows, at least 40% (based on dollar amount invested) of the Municipal Securities in which the Fund invests would be issued by issuers with total outstanding debt issuances that, in the aggregate, have a minimum amount of municipal debt outstanding at the time of purchase of $50 million or more.

The Commission believes that, because this Fund is a series of Managed Fund Shares under Nasdaq Rule 5735, it is reasonable and appropriate for the Exchange to use the Active ETF Generic Listing Standards of Nasdaq Rule 5735 as a point of comparison, rather than to apply the 5705-Related Representations from the Prior Release, which were based on standards applicable to the listing and trading of Index Fund Shares.[36] The Exchange acknowledges that the 40/50 Representation is less stringent than the 40/75 Representation provided in the Prior Release. The Commission notes, however, that the Exchange's proposed 40/50 Representation is consistent with similar requirements applicable to other series of Managed Fund Shares that invest in municipal securities.[37] The Commission also notes that, according to the Exchange, the ''Industry/State Representations'' from the Prior Release would remain in effect with respect to this Fund.

The Commission further notes that, as part of the proposed New Representations, the Exchange has made the following additional representations with respect to the Fund and the requirements applicable to its Municipal Securities investments:

(1) No component fixed income security (excluding the U.S. government securities described under the heading ''Other Investments'' in the Prior Release) would represent more than 15% of the Fund's net assets, and the five most heavily weighted component fixed income securities in the Fund's portfolio (excluding U.S. government securities) would not, in the aggregate, account for more than 25% of the Fund's net assets.[38]

(2) Under normal market conditions, except for the initial invest-up period and periods of high cash inflows or outflows, the Fund's portfolio of Municipal Securities would include securities from a minimum of 30 non-affiliated issuers.[39]

(3) Under normal market conditions, except for the initial invest-up period and periods of high cash inflows or outflows, component securities that in the aggregate account for at least 90% of the weight of the Fund's portfolio of Municipal Securities would be exempted securities as defined in Section 3(a)(12) of the Act.[40]

(4) To the extent the Fund invests in Municipal Securities that are mortgage-backed or asset-backed securities, such investments would not account, in the aggregate, for more than 20% of the weight of the fixed income portion of the Fund's portfolio.[41]

(5) No more than 20% of the Fund's assets will be invested in OTC Derivatives, and, for purposes of calculating this limitation, the Fund's investment in the OTC Derivatives would be calculated as the aggregate gross notional value of the OTC Derivatives.

The Exchange also proposes to change the description of certain fund investments to remove references to ''exempted securities'' as a redundancy because Section 3(a)(12) of the Act exempts certain Municipal Securities. The Commission believes that this clarifying change is reasonable, in light of the representations provided by the Exchange with respect to the Fund's Municipal Securities investment restrictions.

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[33] 15 U.S.C. 78f.

[34] In approving this proposed rule change, the Commission notes that it has considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[35] 15 U.S.C. 78f(b)(5).

[36] *See supra* note 9 (order approving the adoption of generic listing standards for Managed Fund Shares).

[37] *See, e.g.,* Securities Exchange Act Release No. 80745 (May 23, 2017), 82 FR 24755 (May 30, 2016) (SR–NASDAQ–2017–033) (order approving the listing and trading of shares of the First Trust California Municipal High Income ETF) (''CA Municipal ETF'').

[38] *See* Nasdaq Rule 5735(b)(1)(B)(ii) (requiring that no component fixed income security (excluding U.S. Treasury securities and government-sponsored entity (''GSE'') securities) may represent more than 30% of the fixed income weight of the portfolio, and that the five most heavily weighted component fixed income securities in the portfolio (excluding U.S. Treasury securities and GSE securities) may not in the aggregate account for more than 65% of the fixed income weight of the portfolio).

[39] The Exchange has clarified that, for purposes of this restriction, each state and each separate political subdivision, agency, authority, or instrumentality of such state, each multi-state agency or authority, and each guarantor, if any, would be treated as separate, non-affiliated issuers of Municipal Securities. *See* Nasdaq Rule 5735(b)(1)(B)(iii) (requiring that an underlying portfolio that includes fixed income securities, excluding exempted securities, must include a minimum of 13 non-affiliated issuers). The Exchange further clarifies that if the Fund's portfolio of Municipal Securities is composed entirely of securities that meet the definition of ''municipal securities'' set forth in Section 3(a)(29) of the Act, then the portfolio would also be composed entirely of ''exempted securities'' as defined in Section 3(a)(12) of the Act and, therefore, the requirements of Rule 5735(b)(1)(B)(iii) would not pertain to the portfolio.

[40] *See* Nasdaq Rule 5735(b)(1)(B)(iv)(d). *See also id.* (describing Nasdaq Rule 5735(b)(1)(B)(iii) and applicability of this requirement if the Fund's portfolio of Municipal Securities is comprised entirely of securities that meet the definition of ''exempted securities'' under the Act).

[41] *See* Nasdaq Rule 5735(b)(1)(B)(v) (requiring that non-agency, non-GSE and privately-issued mortgage-related and other asset-backed securities components of a portfolio must not account, in the aggregate, for more than 20% of the weight of the fixed income portion of the portfolio).

The Commission notes that the Exchange has represented that, other than the proposed changes, the Fund and the Shares will comply with all other initial and continued listing requirements under Nasdaq Rule 5735. The Commission notes that, according to the Exchange, there is no change to the Fund's investment objectives and that, except as provided herein, all other facts presented and representations made in the Prior Release would remain unchanged. Specifically, the Commission notes that in the Prior Release, the Exchange represented that all statements and representations made in the proposed rule change regarding (a) the description of the portfolio, (b) limitations on portfolio holdings or reference assets, or (c) the applicability of Exchange rules and surveillance procedures constitute continued listing requirements for listing the Shares on the Exchange. In addition, the issuer has represented to the Exchange that it will advise the Exchange of any failure by the Fund to comply with the continued listing requirements, and, pursuant to its obligations under Section 19(g)(1) of the Act, the Exchange will monitor for compliance with the continued listing requirements. If the Fund is not in compliance with the applicable listing requirements, the Exchange will commence delisting procedures under the Nasdaq 5800 Series.[42]

This approval order is based on all of the Exchange's representations, including those set forth above, in the Notice, and in the Prior Release, as applicable, and the Exchange's description of the Fund. The Commission notes that the Fund and the Shares must comply with the requirements of Nasdaq Rule 5735 to be listed and traded on the Exchange.

For the foregoing reasons, the Commission finds that the proposed rule change, as modified by Amendments No. 1 and 2, is consistent with Section 6(b)(5) of the Act[43] and the rules and regulations thereunder applicable to a national securities exchange.

IV. Solicitation of Comments on Amendment No. 1 to the Proposed Rule Change

Interested persons are invited to submit written data, views, and arguments concerning whether Amendment No. 1 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–2017–038 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–2017–038. 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–NASDAQ–2017–038, and should be submitted on or before August 25, 2017.

V. Accelerated Approval of Proposed Rule Change, as Modified by Amendments No. 1 and 2

The Commission finds good cause to approve the proposed rule change, as modified by Amendments No. 1 and 2, prior to the thirtieth day after the date of publication of notice of the filing of Amendment No. 1 in the **Federal Register**. In Amendment No. 1, the Exchange: (a) Modified the requirement that the Fund invest at least 65% of its net assets in Municipal Securities that are rated below investment grade to at least 50% of its net assets; (b) modified the limitation that the Fund invest up to 35% of its net assets in investment grade Municipal Securities to up to 50% of its net assets; and (c) removed references to the Liquidity Rule.

The Commission notes that Amendment No. 1 supplements the proposed rule change by providing additional information regarding the scope of the Fund's permitted investments in investment grade and below investment grade Municipal Securities. The Commission believes that the proposed change to the Fund's investment parameters does not change the Commission's determination in the Prior Release that the listing and trading of the Shares on the Exchange is consistent with the requirements of the Act. In addition, the Commission believes that Amendment No. 1 clarifies the proposed rule change by deleting references to the Liquidity Rule under the 1940 Act. The Commission believes that Amendment No. 1 does not raise any novel or unique regulatory issues under the Act. The changes and additional information in Amendment No. 1 helped the Commission to evaluate whether the listing and trading of the Shares would be consistent with the protection of investors and the public interest. Accordingly, the Commission finds good cause, pursuant to Section 19(b)(2) of the Act,[44] to approve the proposed rule change, as modified by Amendments No. 1 and 2, on an accelerated basis.

VI. Conclusion

It is therefore ordered, pursuant to Section 19(b)(2) of the Exchange Act,[45] that the proposed rule change (SR–NASDAQ–2017–038), as modified by Amendments No. 1 and 2 be, and it hereby is, approved on an accelerated basis.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[46]

Eduardo A. Aleman,

Assistant Secretary.

[FR Doc. 2017–16400 Filed 8–3–17; 8:45 am]

BILLING CODE 8011–01–P

[42] *See supra* note 7.

[43] 15 U.S.C. 78f(b)(5).

[44] 15 U.S.C. 78s(b)(2).

[45] *Id.*

[46] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–81262; File No. SR–CBOE–2017–056]

Self-Regulatory Organizations; Chicago Board Options Exchange, Incorporated; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend Rule 6.1, Days and Hours of Business, To Clarify the Trading Hours for Options on Exchange-Traded Funds and Exchange-Traded Notes

July 31, 2017.

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 17, 2017, Chicago Board Options Exchange, Incorporated (the ''Exchange'' or ''CBOE'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I and II, below, which Items have been prepared by the Exchange. The Exchange filed the proposal as a ''non-controversial'' proposed rule change pursuant to Section 19(b)(3)(A)(iii) of the Act [3] and Rule 19b–4(f)(6) thereunder.[4] The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The purpose of this filing is to amend CBOE Rule 6.1 to clarify the trading hours for options on exchange-traded funds (''ETF's'') and exchange-traded notes (''ETNs''). The text of the proposed rule change is provided below.

(additions are *italicized;* deletions are [bracketed])

* * * * *

Chicago Board Options Exchange, Incorporated Rules

* * * * *

Rule 6.1. Days and Hours of Business

The Board shall determine by resolution the days the Exchange shall be open for business and the Regular Trading Hours and Extended Trading Hours of such days during which transactions may be made on the Exchange.

. . . Interpretations and Policies

.01 (a) Regular Trading Hours. The Board of Directors has resolved that, except under unusual conditions as may be determined by the Board or its designee, Regular Trading Hours during which transactions in options on individual stocks may be made on the Exchange shall correspond to the normal hours for business established by the exchanges currently trading the stocks underlying CBOE options.

(b) No change.

.02 No change.

.03 *Regular Trading Hours. Options on units (or ETFs), as defined under Interpretation and Policy .06 to Rule 5.3, and options on Index-Linked Securities (or ETNs), as defined under Interpretation and Policy .13 to Rule 5.3, may remain open for trading beyond 3:00 p.m. but in no case later than 3:15 p.m. (CT), as designated by the Exchange.*

[(a) Options on Units (or ETFs). Regular Trading Hours for options on Units, as defined under Interpretation and Policy .06 to Rule 5.3, and options on the PowerShares QQQ Trust (''QQQQ'') will last until 3:15 p.m. (CT) each business day.

(b) Options on Index-Linked Securities (or ETNs). Regular Trading Hours for options on Index-Linked Securities, as defined under Interpretation and Policy .13 to Rule 5.3, will last until 3:15 p.m. (CT) each business day.]

.04—.05 No change.

* * * * *

The text of the proposed rule change is also 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

The purpose of this filing is to amend CBOE Rule 6.1 to clarify the trading hours for options on exchange-traded funds (''ETF's'') and exchange-traded notes (''ETNs''). Specifically, the Exchange seeks to amend Interpretation and Policy .03 to Rule 6.1 to provide that options on ETF's and ETNs (collectively exchange-traded products or ''ETPs'') may be traded on the Exchange until 3:15 p.m. (CT) each business day. The Exchange notes that the proposed rule is based on C2 Options Exchange, Incorporated (''C2'') Rule 6.1 and NYSE MKT LLC (''NYSE MKT'') Rule 901NY Commentary .02.

Currently, Rule 6.1 provides that all options on ETPs will be traded on the Exchange until 3:15 p.m. (CT); however, industry practice and the Exchange's current practice allow the vast majority of options on ETPs to be traded until 3:00 p.m. (CT), while allowing certain options on ETPs to trade until 3:15 p.m. (CT).[5] This filing seeks to align CBOE Rules with industry practice.

2. Statutory Basis

The Exchange believes the proposed rule change is consistent with the Securities Exchange Act of 1934 (the ''Act'') and the rules and regulations thereunder applicable to the Exchange and, in particular, the requirements of Section 6(b) of the Act.[6] Specifically, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5) [7] requirements that the rules of an exchange be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest. Additionally, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5) [8] requirement that the rules of an exchange not be designed

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] 15 U.S.C. 78s(b)(3)(A)(iii).

[4] 17 CFR 240.19b–4(f)(6).

[5] *See e.g.,* the trading hours of options on NYSE MKT and NYSE Arca Inc., available at, *https://www.nyse.com/markets/hours-calendars.*

[6] 15 U.S.C. 78f(b).

[7] 15 U.S.C. 78f(b)(5).

[8] *Id.*

to permit unfair discrimination between customers, issuers, brokers, or dealers.

In particular, the proposed rule change will protect investors and the public interest by reducing potential confusing regarding CBOE's trading hours for options on ETPs and aligning CBOE's Rules regarding trading orders for options on ETPs with industry practice. The Exchange notes that the proposed rule is based on C2 Rule 6.1 and NYSE MKT Rule 901NY Commentary .02.

B. Self-Regulatory Organization's Statement on Burden on Competition

CBOE does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The proposed rule change will not impose any burden on intermarket or intramarket competition as the proposed rule change will align CBOE's Rules regarding trading orders for options on ETPs with industry practice. In addition, the proposed rule change does not modify the construct for trading hours but simply identifies the products that may close at 3:00 p.m. (CT) or 3:15 p.m. (CT), which is consistent with the industry.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange neither solicited nor received comments on the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A)(iii) of the Act [9] and subparagraph (f)(6) Rule 19b-4 thereunder.[10]

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–2017–056 on the subject line.*

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–CBOE–2017–056. 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–2017–056 and should be submitted on or before August 25, 2017.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[11]

Eduardo A. Aleman,

Assistant Secretary.

[FR Doc. 2017–16397 Filed 8–3–17; 8:45 am]

BILLING CODE 8011–01–P

[9] 15 U.S.C. 78s(b)(3)(A).

[10] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6)(iii) requires the Exchange to give the Commission written notice of the Exchange's intent to file the proposed rule change, along with a brief description and text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

[11] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–81270; File No. SR–Phlx–2017–56]

Self-Regulatory Organizations; NASDAQ PHLX LLC; Notice of Filing of Proposed Rule Change to a Proposal To Amend Rule 1027, Discretionary Accounts, To Conform It More Closely to a Comparable Rule of the Chicago Board Options Exchange (''CBOE'') and To Make Minor Corrections and Clarifications

July 31, 2017.

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 20, 2017, NASDAQ PHLX LLC (''Phlx'' or ''Exchange'') filed with the Securities and Exchange Commission (''SEC'' or ''Commission'') the proposed rule change as described in Items I, II, and III, below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend Rule 1027, Discretionary Accounts, to conform it more closely to a comparable rule of the Chicago Board Options Exchange (''CBOE'') and to make minor corrections and clarifications.

The text of the proposed rule change is available on the Exchange's Web site at *http://nasdaqphlx.cchwallstreet.com/,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

Rule 1027 generally imposes restrictions and various requirements on members [3] and partners and employees of member organizations [4] regarding the exercise of discretionary power with respect to trading in options in a customer's accounts. The Exchange proposes to amend Rule 1027 in a number of respects to eliminate redundant rule text, clarify certain rule text, and conform parts of the rule more closely to CBOE Rule 9.10, Discretionary Account.[5]

Rule 1027(a)

Rules 1027(a)(i) and (ii) apply to stock or exchange-traded fund share options and foreign currency options respectively. These provisions prohibit the exercise of any discretionary power with respect to trading in options contracts in a customer's account unless such customer has given prior written authorization with respect to such trading and the account has been accepted in writing by a designated Registered Options Principal or, in the case of foreign currency options, a Foreign Currency Options Principal.

Rule 1027(a)(i) is proposed to be amended to include index options, as their current exclusion from the rule is without a rational basis and was likely an oversight. References to Registered Options Principal ''qualified persons'' or ''qualified individuals'' in Rule 1027(a)(i) are proposed to be amended in order to refer only to ''Registered Options Principals,'' in order to eliminate needless ambiguity and lack of clarity as to who is a Registered Options Principal ''qualified person'' or ''qualified individual.'' Additionally, the last two sentences of Section (a)(i) currently provide that every discretionary order shall be identified as discretionary at the time of entry, and that discretionary accounts shall receive frequent review by a Registered Options Principal qualified person specifically delegated such responsibilities under Rule 1025, who is not exercising the discretionary authority. These sentences are largely duplicative of existing Rule 1027(a)(iii) and are therefore proposed to be deleted. The rule would be expanded to cover member organizations, to be more consistent with the comparable CBOE rule which applies to CBOE Trading Permit Holder (''TPH'') organizations.[6]

The Exchange proposes to delete from Section (a)(iii) a reference to ''Compliance Registered Option Principal,'' a term which the Exchange no longer uses, and proposes to substitute the term ''Registered Options Principal.'' It also proposes to amend that section by adding language requiring the Registered Options Principal providing appropriate supervisory review to be specifically delegated such responsibilities under Rule 1025 and not be the Registered Options Principal exercising the discretionary review. These changes would conform Section (a)(iii) to the duplicative language deleted from Section (a)(i) as described above. The Exchange also proposes to delete the last sentence of Section (a)(iii), which provides that the provisions of paragraph (a) shall not apply to discretion as to the price at which or the time when an order given by a customer for the purchase or sale of a definite number of option contracts in a specified security or foreign currency shall be executed. This sentence is largely duplicative of existing language in Rule 1027(e), Discretion as to Time or Price Excepted. Rule 1027(e), however, is proposed to be amended by the addition of a reference to ''foreign currency'' which was present in the deleted sentence of Section (a)(iii).

The Exchange is proposing no changes to section (a)(iv) which extends the provisions of Rule 1027 to index warrants, as no changes are required.

Rule 1027(c) Prohibited Transactions

Currently, Rule 1027(c) prohibits members as well as partners, officers and employees of a member organization having discretionary power over a customer's account from, in the exercise of such discretion, executing or causing to be executed therein any purchases or sales of option contracts which are excessive in size or frequency in view of the financial resources in such account. The prohibition is proposed to be reworded, to conform Phlx Rule 1027(c) more closely to CBOE Rule 9.10, Discretionary Accounts, section (c). Additionally, the rule would be expanded to cover member organizations as well as members and partners and employees of member organizations.

Rule 1027(d) Record of Transactions

Rule 1027(d) currently requires a record to be made of every transaction in option contracts in respect to which a member or a partner, officer or employee of a member organization has exercised discretionary authority, clearly reflecting such fact and indicating the name of the customer, the designation and number of the option contracts, the premium and the date and time when such transaction was

[3] Exchange Rule 1(n) defines ''member'' as a permit holder which has not been terminated in accordance with the By-Laws and Rules of the Exchange. The Exchange has issued ''Series A–1'' permits, which confer on the holder rights and privileges, and impose on the holder the obligations, set forth in Exchange Rule 908. Under Exchange Rule 908(b) a Series A–1 permit may only be issued to an individual who is a natural person of at least twenty-one (21) years of age, or to a corporation meeting the eligibility and application requirements set forth in the By-Laws and Rules.

[4] Rule 1(o) defines ''member organization'' as ''a corporation, partnership (general or limited), limited liability partnership, limited liability company, business trust or similar organization, transacting business as a broker or a dealer in securities and which has the status of a member organization by virtue of (i) admission to membership given to it by the Membership Department pursuant to the provisions of Rules 900.1 or 900.2 or the By-Laws or (ii) the transitional rules adopted by the Exchange pursuant to Section 6–4 of the By-Laws.'' Rule 901(a) provides in part that ''[t]he Membership Department shall have jurisdiction over the issuance of memberships (in respect of members and member organizations) and permits and over applications by non-members for admission as members.'' Rule 901(c) provides that ''[a]ll applications to qualify and register a corporation or other entity as a member organization and all applications for reinstatement of any qualification or registration of a member organization shall be referred to the Membership Department which shall investigate and act thereon.''

[5] CBOE Rule 9.10 was substantially amended in Securities Exchange Act Release No. 56492 (September 21, 2007), 72 FR 54952 (September 27, 2007) (SR–CBOE–2007–106) to create a supervisory structure for options that is similar to that required by New York Stock Exchange (''NYSE'') and National Association of Securities Dealers (''NASD'') rules. On July 26, 2007, the Commission approved a proposed rule change filed by NASD to amend NASD's Certificate of Incorporation to reflect its name change to Financial Industry Regulatory Authority Inc., or FINRA, in connection with the consolidation of the member firm regulatory functions of NASD and NYSE Regulation, Inc. See Securities Exchange Act Release No. 56146 (July 26, 2007).

[6] Rule 1027(a)(ii) deals with foreign currency options and has no counterpart in CBOE Rule 9.10(a). The Exchange is nevertheless proposing to revise Rule 1027(a)(ii) by expanding its scope to include member organizations for consistency with Rule 1027(a)(i) in terms of extent of coverage of the rule.

effected. The Exchange proposes to reword the rule so that it applies to option transactions for an account in respect to which a member or member organization or a partner, officer or employee of a member organization is vested with any discretionary authority, and to detail the required content of the record. The revision proposed for Rule 1027(d) would conform the rule more closely to CBOE Rule 9.10, Discretionary Accounts, section (b), which extends to CBOE TPH organizations, except that the Exchange proposes to retain the existing requirement that the transaction record clearly reflect that the member (or, as the rule is proposed to be amended, member organization) or a partner, officer or employee of a member organization has exercised discretionary authority, as the Exchange believes this to be important information with respect to a transaction.

Rule 1027(e)

As discussed above the Exchange proposes to amend Rule 1027(e), which generally excludes price and time discretion from the requirements of Rule 1027, to cover foreign currency options. The Exchange also proposes to correct an internal cross reference to ''this paragraph (d)'' which should read ''this paragraph (e)''.

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act,[7] in general, and furthers the objectives of Section 6(b)(5) of the Act,[8] in particular, in that it is designed to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general to protect investors and the public interest. The amendment of the requirements associated with discretionary accounts should remove impediments to and perfect the mechanism of a free and open market and a national market system, by eliminating redundant rule text, clarifying certain rule text, and conforming parts of the rule more closely to CBOE Rule 9.10, Discretionary Accounts which should create greater regulatory parity among options exchanges regarding obligations toward customers' discretionary accounts—reducing a source of potential regulatory arbitrage—and by creating more efficient regulatory compliance by members of both exchanges due to reduction of differences in wording and consequent potential for inadvertent regulatory noncompliance. The Exchange believes it is in the public interest for a more consistently worded regulatory policy and standard regarding discretionary accounts to be in effect across options exchanges, for the benefit of customers. The harmonized rules are designed to further the goal of harmonized examinations and enforcement of similar rules, thus reducing duplicative regulatory efforts, thus lowering regulatory cost passed on to member organizations and the general public.

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

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 45 days of the date of publication of this notice in the **Federal Register** or within such longer period (i) as the Commission may designate up to 90 days of such date if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the Exchange consents, the Commission shall: (a) By order approve or disapprove such proposed rule change, or (b) institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–Phlx–2017–56 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–Phlx–2017–56. 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–Phlx–2017–56 and should be submitted on or before August 25, 2017.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[9]

Eduardo A. Aleman,

Assistant Secretary.

[FR Doc. 2017–16405 Filed 8–3–17; 8:45 am]

BILLING CODE 8011–01–P

[7] 15 U.S.C. 78f(b).

[8] 15 U.S.C. 78f(b)(5).

[9] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–81264; File No. SR–MSRB–2017–05]

Self-Regulatory Organizations; Municipal Securities Rulemaking Board; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Assess an Underwriting Fee on Dealers That Are Underwriters of Primary Offerings of Plans

July 31, 2017.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the ''Act'' or ''Exchange Act'') [1] and Rule 19b–4 thereunder,[2] notice is hereby given that on July 19, 2017 the Municipal Securities Rulemaking Board (''MSRB'' or ''Board'') filed with the Securities and Exchange Commission (''Commission'' or ''SEC'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the MSRB. 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 MSRB filed with the Commission a proposed amendment to MSRB Rule A–13, on underwriting and transaction assessments for brokers, dealers and municipal securities dealers (collectively ''dealers''), to assess an underwriting fee on dealers that are underwriters of primary offerings of plans, as the terms ''underwriter'' and ''plan'' are defined under MSRB Rule G–45, on reporting of information on municipal fund securities (the ''proposed rule change'').[3] The MSRB has designated the proposed rule change for immediate effectiveness. Beginning in May 2018, the Board will invoice underwriters for the assessments due under the proposed rule change. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

The text of the proposed rule change is available on the MSRB's Web site at *www.msrb.org/Rules-and-Interpretations/SEC-Filings/2017-Filings.aspx,* at the MSRB'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 MSRB 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 MSRB 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 assess an underwriting fee on underwriters to plans to defray the costs and expenses of operating and administering the MSRB. The proposed rule change will amend Rule A–13 to add a new fee on an underwriter to a plan at a rate of .0005% ($.005 per $1,000) of the total aggregate assets for the plan underwritten as of December 31 each year, as reported on MSRB Form G–45, reporting of information on municipal fund securities. The MSRB believes that the proposed fee is reasonable as well as necessary and appropriate to help defray the costs of operating and administering the MSRB. The MSRB is committed to appropriately and equitably assessing fees across all regulated activities to ensure fairness, and, as summarized below, the MSRB's activity concerning underwriters to plans has historically been funded with minimal fees.

Background

A. MSRB's Regulatory Authority Over Dealers and Underwriters to Plans

The MSRB's regulation of dealers that sell interests in and dealers that are underwriters to plans began over 18 years ago. In 1998, after certain states created 529 college savings plans,[4] the MSRB contacted the SEC to determine whether plan investments were securities and, further, whether they were municipal securities under the federal securities laws.[5] In early 1999, in response to the MSRB's inquiry, SEC staff informed the Board that ''at least some interests in . . . higher education trusts may be, depending on the facts and circumstances, 'municipal securities' for purposes of the Exchange Act.'' [6] Based on that guidance, the MSRB began its regulation of dealer and underwriter activity in plans and local government investment pools,[7] collectively known as municipal fund securities under Rule D–12, ''municipal fund security.'' Further, the Board expanded its mission to include, among other things, the protection of investors in plans and the public interest by promoting a fair and efficient market for interests in those plans.

To support the MSRB's regulation of dealers that are underwriters to plans, as well as its mission to protect investors in those plans, the MSRB has engaged in significant rulemaking, market transparency, educational and market outreach initiatives. In addition, the MSRB has provided examination and enforcement support to other regulatory agencies related to dealer activity regarding plans. Those initiatives and support require the Board's resources, including the resources of its staff and of its Electronic Municipal Market Access (EMMA®) [8] system.

i. Rulemaking Initiatives

Approximately one third of the MSRB's general rules specifically

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[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] Under Rule G–45(d)(xiv), an ''underwriter'' shall mean a dealer that is an underwriter, as defined in Rule 15c2–12(f)(8) under the Act, of municipal fund securities that are not local government investment pools.

Under Rule G–45(d)(ix), a ''plan'' is a college savings plan or program established by a state, or agency or instrumentality of a state, to operate as a qualified tuition program in accordance with Section 529 of the Internal Revenue Code of 1986, as amended. The proposed rule change will not apply to underwriters of other types of municipal fund securities.

[4] A 529 college savings plan is a plan, as defined under Rule G–45(d)(ix).

[5] Section 529(b)(1) of the Internal Revenue Code of 1986, as amended (the ''Code'') provides, in part, that a 529 college savings plan is a ''program established and maintained by a State or agency or instrumentality thereof.'' 26 U.S.C. 529(b)(1).

Although Congress amended the Code to add Section 529 in 1996, the market for 529 college savings plans did not grow significantly until after the enactment of the Economic Growth and Tax Relief Reconciliation Act of 2001 (''EGTRRA''). EGTRRA made several improvements, such as permitting distributions to be withdrawn free of federal income tax, if the distributions were used for qualified higher education expenses.

[6] Letter dated February 26, 1999 from Catherine McGuire, Chief Counsel, Division of Market Regulation, SEC, to Diane G. Klinke, General Counsel of the Board, in response to letter dated June 2, 1998 from Diane G. Klinke to Catherine McGuire.

[7] Local government investment pools (''LGIPs'') are established by state or local governmental entities as trusts that serve as vehicles for the pooled investment of public moneys of participating governmental entities. Although most LGIPs are fully administered by governmental personnel or non-dealer contractors, a limited number of LGIPs involve dealers undertaking transaction-based activities. Such dealers are subject to the MSRB's rules regarding municipal fund securities.

[8] EMMA is a registered trademark of the MSRB, and is the official repository for information on virtually all municipal bonds, providing free access to official disclosures, trade data and other information about the municipal securities market.

address municipal fund securities. The MSRB's rulemaking relating to dealers that sell interests in and dealers that are underwriters to plans has addressed, among other areas, professional qualifications (*e.g.,* the MSRB added a new permanent category of principal—Series 51—municipal fund securities limited principal—to supervise activities regarding plans under Rule G–3, on professional qualification requirements),[9] fair practice (*e.g.,* the Board addressed under Rule G–20, on gifts, gratuities, non-cash compensation and expenses of issuance, promotional gifts and ''other business logos'' of a 529 college savings plan for which a dealer is acting as a distributor,[10] and advertising, including a proposed rule change relating to municipal fund security product advertisements submitted to the Commission on June 22, 2017, under Rule G–21(e), on municipal fund security product advertisements),[11] and market transparency (*e.g.,* the Board addressed disclosures in connection with the offering of interests in 529 college savings plans under Rule G–32, on disclosures in connection with primary offerings).[12] Since 2001, the Board has issued over 60 regulatory notices pertaining to plans. Many of those notices provided guidance to dealers regarding the application of existing MSRB rules to plans.

ii. Market Transparency Initiatives

The MSRB has engaged in several market transparency initiatives relating to municipal fund securities. For example, under MSRB Rule G–32, on disclosures relating to primary offerings, an underwriter to a plan, among other things, must submit the official offering statement and any amendment thereto, *i.e.,* the program disclosure booklet for the plan it distributes, to the MSRB. To assist the underwriter in making its submission, the MSRB developed a filing portal on EMMA as well as the database for the underwriter's submissions. In addition, to assist an investor with finding the program disclosure booklet for a plan of interest, the MSRB developed an interactive Web site with a 50-state map that allows the investor to more quickly and easily access that information.

Under Rule G–45, an underwriter must submit information about each plan for which it is an underwriter on a semi-annual basis to the MSRB. To facilitate such submissions, the MSRB developed two methods through which an underwriter could make those submissions to the MSRB so that the underwriter could select the method it prefers (either through the EMMA dataport or through a computer-to-computer interface) as well as developed the database for the submissions. The MSRB continues to enhance the database as well as to assist underwriters to plans by answering inquiries relating to the submission of that data through the MSRB's call center. Further, MSRB staff utilizes the data submitted under Rule G–45 to analyze plans, monitor their growth rate, size and investment options, and compare plans based on fees, costs, and performance.

iii. Educational and Market Outreach

The MSRB has engaged in educational and market outreach both to underwriters to plans and to investors in those plans. That outreach has included: Conducting regional compliance seminars for dealers; MSRB staff presentations and attendance at major industry conferences; and the development and distribution of multiple educational pieces to assist dealers and investors in 529 college savings plans, including an investor's guide to 529 college savings plans.

iv. Market Leadership Activities

Beyond its rulemaking, market transparency, educational and market outreach initiatives, the MSRB has engaged in market leadership activities relating to plans. Those market leadership activities, among other things, have resulted in Congressional testimony and in the development of voluntary industry disclosure standards for 529 college savings plan program disclosure booklets.[13] For example, MSRB staff testified at a 2004 Senate subcommittee oversight hearing on sales and disclosure practices in the 529 college savings plan market. In addition, the MSRB encouraged the College Savings Plans Network to promulgate more comprehensive voluntary disclosure standards and to establish a central information clearinghouse on 529 college savings plans. Further, in 2009, the MSRB submitted a comment letter on the use of 529 college savings plans in advance of the Report on 529 College Savings Plans prepared by the U.S. Department of the Treasury on behalf of the White House Task Force on the Middle Class.

v. Support to Other Regulatory Agencies

To facilitate efficient and effective examination and enforcement of MSRB rules, the MSRB provides support to the regulatory agencies that enforce the MSRB's rules. Those regulatory agencies include the Financial Industry Regulatory Authority, Inc. (''FINRA'') and the Commission. That support includes education and guidance about MSRB rules, training of the staff of those regulatory agencies regarding the MSRB rules, and the provision of additional information about plans to support the monitoring of the market for potential misconduct. The MSRB continues and will continue in the future to provide this support.

B. Holistic Review of MSRB Fees

The MSRB assesses dealers and municipal advisors (collectively, ''regulated entities'') various fees designed to defray the costs of its operations and administration, including rulemaking, market transparency, educational and market outreach initiatives that fulfill its Congressional mandate to, among other things, protect investors, state and local governments and other municipal entities by promoting the fairness and efficiency of the municipal securities market. Section 15B(b)(2)(J) of the Act[14] provides, in pertinent part, that each regulated entity shall pay to the Board such reasonable fees and charges as may be necessary or appropriate to defray the costs of operating and administering the Board, and that the MSRB shall have rules specifying the amount of such fees. The current MSRB fees are:

1. Initial Registration Fee (Rule A–12, on Registration)

$1,000 one-time registration fee to be paid by each dealer to register with the MSRB before engaging in municipal securities activities and each municipal advisor to register with the MSRB before engaging in municipal advisory activities.

2. Annual Registration Fee (Rule A–12)

$1,000 annual fee to be paid by each dealer and municipal advisor registered with the MSRB.

[9] *See* Exchange Act Release No. 45652 (Mar. 26, 2002), 67 FR 15844 (Apr. 3, 2002), SR–MSRB–2002–03.

[10] *See* Exchange Act Release No. 76381 (Nov. 6, 2015), 80 FR 70271 (Nov. 13, 2015), SR–MSRB–2015–09.

[11] *See* Exchange Act Release No. 81060 (Jun. 30, 2017), 82 FR 31644 (Jul. 7, 2017), SR–MSRB–2017–04.

[12] *See* Exchange Act Release No. 43858 (Jan. 18, 2001), 66 FR 8126 (Jan. 29, 2001), SR–MSRB–00–06.

[13] The MSRB's Web site discusses the Board's market leadership activities. *http://www.msrb.org/Market-Topics.aspx.*

[14] 15 U.S.C. 78*o*–4(b)(2)(J).

3. Underwriting Fee (Rule A–13)

$.0275 per $1,000 of the par value paid by a dealer, on all municipal securities purchased from an issuer by or through such dealer, whether acting as principal or agent as part of a primary offering—except that this fee does not apply to commercial paper or municipal fund securities, such as interests in plans.

4. Transaction Fee (Rule A–13)

.001% ($.01 per $1,000) of the total par value to be paid by a dealer, except in limited circumstances, for inter-dealer sales and customer sales reported to the MSRB pursuant to Rule G–14(b), on transaction reporting requirements—this fee does not apply to the sale of interests in plans.

5. Technology Fee (Rule A–13)

$1.00 paid by a dealer per transaction for each inter-dealer sale and for each sale to customers reported to the MSRB pursuant to Rule G–14(b)—this fee does not apply to the sale of interests in plans.

6. Municipal Advisor Professional Fee (Rule A–11, on Assessments for Municipal Advisor Professionals)

$300 per Form MA–I on file with the SEC by the municipal advisor—this fee does not apply to dealers/underwriters to plans.

7. Examination Fee (Rule A–16, on Examination Fees)

$150 test development fee assessed per candidate for each MSRB examination.

8. Late Fee (Rule A–11 and Rule A–12)

$25 monthly late fee and a late fee on the overdue balance (computed according to the prime rate) until paid on balances not paid within 30 days of the invoice date by the dealer or municipal advisor.[15]

Begun in 2015, the Board's holistic review of fees that the Board assesses on regulated entities continues. The Board evaluates those fees with the goal of better aligning revenue sources with operating expenses and all capital needs. The Board strives to diversify funding sources among regulated entities and other entities that fund MSRB services in a manner that ensures long-term sustainability, while continuing to strike an equitable balance among regulated entities and a fair allocation of the expenses of the regulatory activities, systems development and operational activities undertaken by the MSRB. Proxies used by the Board for fairly allocating to regulated entities the cost of MSRB regulation include, but are not limited to: Being registered to engage in municipal securities or municipal advisory activities; the level of dealer market activity; and the number of associated persons engaged in municipal advisory activities on behalf of a municipal advisor. Recognizing that in any given year there could be more or less activity by a particular class of regulated entities, the Board, as it has historically, sought to establish a fee structure that would result in a balanced and reasonable contribution over time from all regulated entities to defray costs and expenses of operating and administering the MSRB.

The Board's most recent evaluation focused on the fees assessed on dealers/underwriters to 529 college savings plans. Of the fees assessed to defray the costs of operating and administering the Board, dealers that sell interests in and dealers that act as underwriters to plans, that do not otherwise engage in the municipal securities business, are subject to three MSRB fees—the initial and annual registration fees, the examination fees, and the late fees (when applicable). During Fiscal Year 2016, the annual registration fees assessed on all regulated entities accounted for slightly less than 6% of the Board's total revenue, and of that amount, registration fees for dealers/underwriters that engage in transactions relating to plans exclusively accounted for 0.9% of that slightly less than 6% of registration fee revenue, or less than 0.05% of total revenue.

In 1999, the Board requested comment about a draft amendment to Rule A–13 to assess an underwriting fee on underwriters to plans.[16] The draft underwriting fee applicable to underwriters of plans would have been assessed at the same level as the underwriting fee then assessed on underwriters of municipal bonds, but based on the purchase price the investor paid for the interests in the plan, exclusive of any commission. In addition, the draft underwriting fee would not have accounted for the redemption of interests in plans. The Board, however, did not proceed with that draft amendment to Rule A–13. The Board stated that:

> Based on the . . . continuous nature of offerings in municipal fund securities, the programmatic nature of most customer investments and the heightened potential that underwriting assessments could create significant financial burdens on issuers to their customers' detriment justify caution in imposing the underwriting assessment.[17]

The Board has exercised that caution, and now has determined to assess an underwriting fee on dealers that are underwriters to plans at a level far below the underwriting fee assessed on underwriters of municipal bonds. As noted under ''Proposed Rule Change,'' underwriters, consistent with the Board's long-standing prohibition, will be prohibited under Rule A–13 from charging or otherwise passing through the underwriting fee to issuers of plans.

Proposed Rule Change

The proposed rule change will assess an underwriter to a primary offering of a plan an underwriting fee of .0005% of the total aggregate assets of the plan for the reporting period ending December 31 each year, as required to be reported on Form G–45. For the purposes of the proposed rule change, if there are multiple underwriters of the primary offering of the interests in plans identified on Form G–45, the term ''underwriter'' will be limited to the underwriter identified as the primary distributor in the official statement, *i.e.,* the program disclosure booklet, for the primary offering submitted under Rule G–32. The Board will invoice that primary distributor for the assessment due under the proposed rule change beginning in May 2018.

Specifically, the proposed rule change will amend Rule A–13(a) to reflect the amount of the proposed rule change's underwriting fee set forth in new subsection (c)(ii). The proposed rule change also will amend Rule A–13 to add new section (b) ''underwriting assessments—certain municipal fund securities'' to Rule A–13. New section (b) will require that an underwriter to a plan pay an underwriting fee to the Board. As noted above, for the purposes of that new section, if there are multiple

[15] In addition, the MSRB charges data subscription and service fees for subscribers, including dealers and municipal advisors, seeking direct electronic delivery of municipal trade data and disclosure documents associated with municipal bond issues. However, this information is available without direct electronic delivery on the EMMA Web site without charge.

[16] *See* Request for Comments (March 17, 1999) (the ''March request''). In response to the March request, commenters submitted that the fee structure for dealers involved in the distribution of 529 college savings plans was more like an administrative fee, and was significantly different from an underwriting discount or commission since such dealers did not undertake underwriting risks. Commenters also urged, if underwriting assessments were assessed, that assessments be lower than the assessments charged in more traditional municipal securities offerings and that the assessments consider any securities that are retired/redeemed. Commenters noted that the underlying mutual funds offered through a 529 college savings plan pay registration fees to the SEC.

[17] *See* File No. SR–MSRB–00–6 (Apr. 5, 2000).

underwriters for the plan identified on MSRB Form G–45, the term ''underwriter'' will be limited to the underwriter identified as the primary distributor in the official statement for the primary offering submitted under Rule G–32 as of December 31 of the relevant year. The proposed rule change will renumber current section (b) of Rule A–13 as section (c). In new subsection (c)(i), the Board will set forth the underwriting assessment for primary offerings subject to assessment in section (a). In new subsection (c)(ii), the proposed rule change will set forth the amount of the assessment of the underwriting fee on underwriters to plans (.0005% of the total aggregate assets for the reporting period ending December 31 each year, as required to be reported on MSRB Form G–45). The proposed rule change will renumber current section (c) of Rule A–13 as section (d) of Rule A–13. Further, the proposed rule change will renumber current section (d) of Rule A–13 as section (e). New section (e) of Rule A–13 will address the billing procedure as to how the Board will invoice dealers for payment of underwriting assessments and transaction and technology assessments, including dealers that act as underwriters to plans. For the assessments set forth in new sections (c)(i) and (d), the Board monthly will invoice brokers, dealers and municipal securities dealers for payment of underwriting assessments and transaction and technology assessments. For the assessments set forth in new subsection (c)(ii), the Board annually will invoice the underwriter identified in section (b) for the payment of underwriting assessments.

As previously stated, new section (e) will provide that if there are multiple underwriters identified on Form G–45 for the reporting period ending December 31 each year, the Board will invoice the underwriter identified as the primary distributor in the official statement for the primary offering submitted under Rule G–32 of the relevant year. The proposed rule change will renumber current section (e) of Rule A–13 as section (f). The proposed rule change will clarify that the Board's long-standing prohibition on charging or otherwise passing through the fees required under Rule A–13 to issuers applies to all fees assessed under Rule A–13, including underwriting fees assessed on underwriters to plans.[18] Finally, the proposed rule change will renumber current section (f) of Rule A–13 as section (g).

2. Statutory Basis

The MSRB believes that the proposed rule change is consistent with Section 15B(b)(2)(J) of the Act [19] which requires, in part, that the MSRB's rules shall provide that each municipal securities broker, municipal securities dealer, and municipal advisor shall pay to the Board such reasonable fees and charges as may be necessary or appropriate to defray the costs and expenses of operating and administering the Board and that such rules shall specify the amount of such fees and charges.

The MSRB believes that its rules provide for reasonable dues, fees, and other charges among regulated entities. The MSRB believes that the proposed rule change is necessary and appropriate to fund the operation and administration of the Board and satisfies the requirements of Section 15B(b)(2)(J),[20] achieving a more equitable balance among regulated entities and a fairer allocation of the expenses of the regulatory activities, system development, and operational activities undertaken by the MSRB.

The proposed rule change will account for the differences between municipal fund securities and other municipal securities. The Board accounts for those differences both in the manner and in the amount of the underwriting fee that the Board will assess on underwriters to plans.

To recognize the continuous nature of offerings in plans, the MSRB will assess the proposed fee in a manner that will be similar to how the SEC assesses registration fees on mutual funds pursuant to Rule 24f–2 under the Investment Company Act of 1940, as amended. The MSRB will assess the proposed rule change on the plan's total aggregate assets as of December 31 each year, as reported by an underwriter on Form G–45. Thus, the proposed rule change will account for the redemption of units in plans. Further, to recognize the differences in the commission structure between other municipal securities offerings, such as municipal bonds, and offerings in plans, the Board will assess the proposed rule change at a rate that is significantly lower than the rate the Board uses to assess underwriters subject to assessment under Rule A–13(a) (the amount of the underwriting assessment under Rule A–13(a) is .00275% of the par value of the primary offering).

The proposed rule change will defray the costs of the Board's significant rulemaking, market transparency, educational and market outreach initiatives, market leadership, and inspections/enforcement support relating to underwriters to plans, an industry with approximately $266 billion in assets as of December 31, 2016, as reported in March 2017.[21] The proposed rule change will diversify funding sources among regulated entities in a manner that will achieve a more equitable balance among regulated entities and a fairer allocation of the costs, systems, and services among other users and regulated entities. Looking forward to Fiscal Year 2020, the MSRB's pro forma budgets reflect a gradual decrease in reserve levels, even with the new underwriting fee on underwriters of 529 college savings plans, as expenses are projected to increase annually while current sources of revenue are projected to be flat.

B. Self-Regulatory Organization's Statement on Burden on Competition

Section 15B(b)(2)(C) of the Act requires that MSRB rules not be designed to impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act. In accordance with certain aspects of the Board's policy on the use of economic analysis,[22] the Board has reviewed the proposed rule change. The Board believes the

[18] For over twenty years, the Board has stated that:

the fees paid to the Board under rule A–13 should be characterized by dealers to issuers no differently than the annual fees paid to the Board . . . [under Rule A–12] and any other ''overhead'' expenses that are incurred by virtue of the dealer engaging in municipal securities business.

Exchange Act Rel. No. 34601 (Aug. 25, 1994), 59 FR 169 (Sept. 1, 1994) (File No. SR–MSRB–94–12).

[19] 15 U.S.C. 78*o*–4(b)(2)(J). Section 15B(b)(2)(J) provides that each dealer shall:

pay to the Board such reasonable fees and charges as may be necessary or appropriate to defray the costs and expenses of operating and administering the Board. Such rules shall specify the amount of such fees and charges, which may include charges for failure to submit to the Board, or to any information system operated by the Board, within the prescribed timeframes, any items of information or documents required to be submitted under any rule issued by the Board.

[20] *Id.*

[21] *See* Strategic Insight 529 College Savings & ABLE 1Q 2017 529 Data Highlights available at *http://www.529insiders.com/uploadedFiles/529-Insider/News/2017/January/1Q%202017%20Strategic%20Insight%20529%20Data%20Quarterly%20Highlights.pdf.*

[22] The scope of the Board's policy on the use of economic analysis in rulemaking provides that:

[t]his policy addresses rulemaking activities of the MSRB that culminate, or are expected to culminate, in a filing of a proposed rule change with the SEC under Section 19(b) of the Securities Exchange Act of 1934 . . . other than a proposed rule change that the MSRB reasonably believes would qualify for immediate effectiveness under Section 19(b)(3)(A) if filed as such or as otherwise provided under the exception process of this policy.

Policy on the Use of Economic Analysis in MSRB Rulemaking, available at *http://www.msrb.org/en/Rules-and-Interpretations/Economic-Analysis-Policy.*

proposed rule change is necessary and appropriate to ensure that MSRB registrants that participate in the underwriting activities of plans share in the costs and expenses of operating and administering the MSRB. The MSRB has considered the economic impact of the proposed rule change. The MSRB expects the impact of the proposed rule change to be small and unlikely to negatively impact the competitiveness of the underwriters or underwriting markets for 529 college savings plans.

The proposed rule change will assess an annual fee of 0.0005%, or 1/20th of a basis point, on plan assets to underwriters of plans.[23]

In addition, the MSRB 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 purpose of the Act since it will apply equally to all underwriters engaged in a primary offering of interests in plans required to submit data to the MSRB on Form G–45. The assessment will be proportional to the overall size of each plan being underwritten; therefore, the MSRB believes the total fee charged to each underwriter will bear a reasonable relationship to the level of underwriting activities that are undertaken by the underwriter. Moreover, since the proposed rule change's amendment to Rule A–13 will result in an underwriting fee that is *de minimus,* underwriters of 529 college savings plans that are not subject to Rule G–45 will not have an unfair competitive advantage.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Board did not solicit comment on the proposed change. Therefore, there are no comments on the proposed rule change received from members, participants or others.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing proposed rule change has become effective pursuant to Section 19(b)(3)(A) of the Act[24] and paragraph (f) of Rule 19b–4 thereunder.[25] At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–MSRB–2017–05 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549.

All submissions should refer to File Number SR–MSRB–2017–05. 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 MSRB. 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–MSRB–2017–05 and should be submitted on or before August 25, 2017.

For the Commission, pursuant to delegated authority.[26]

Eduardo A. Aleman,

Assistant Secretary.

[FR Doc. 2017–16399 Filed 8–3–17; 8:45 am]

BILLING CODE 8011–01–P

[23] The SEC currently assesses a fee for mutual funds sold annually, which in 2017 amounts to 1.159 basis point per year. The fee rate which the SEC assessed for the mutual funds pursuant to Rule 24f–2 under the Investment Company Act of 1940, as amended, is by law, the same rate as the annual rate assessed for registered securities under Section 6(b) of the Securities Act of 1933, as amended. The SEC determines the fee rate at the beginning of each fiscal year.

[24] 15 U.S.C. 78s(b)(3)(A).

[25] 17 CFR 240.19b–4(f).

[26] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–81260; File Nos. SR–NSCC–2017–803; SR–OCC–2017–804]

Self-Regulatory Organizations; National Securities Clearing Corporation; The Options Clearing Corporation; Notice of No Objection To Advance Notices Concerning the Adoption of a New Stock Options and Futures Settlement Agreement Between the National Securities Clearing Corporation and The Options Clearing Corporation

July 31, 2017.

On June 1, 2017, National Securities Clearing Corporation (''NSCC'') and The Options Clearing Corporation (''OCC,'' each a ''Clearing Agency,'' and collectively, ''Clearing Agencies'') filed with the Securities and Exchange Commission (''Commission'') advance notices SR–NSCC–2017–803 and SR–OCC–2017–804 respectively (collectively, the ''Advance Notices''), pursuant to Section 806(e)(1) of Title VIII of the Dodd-Frank Wall Street Reform and Consumer Protection Act entitled the Payment, Clearing, and Settlement Supervision Act of 2010 (''Clearing Supervision Act'')[1] and Rule 19b–4(n)(1)(i) under the Securities Exchange Act of 1934 (''Act'').[2] The Advance Notices were published for comment in the **Federal Register** on July 5, 2017.[3] The Commission did not

[1] 12 U.S.C. 5465(e)(1).

[2] 17 CFR 240.19b–4(n)(1)(i).

[3] Securities Exchange Act Release Nos. 81039 (June 28, 2017), 82 FR 31123 (July 5, 2017) (SR–NSCC–2017–803); 81040 (June 28, 2017), 82 FR 31109 (July 5, 2017) (SR–OCC–2017–804). The Clearing Agencies also filed proposed rule changes with the Commission pursuant to Section 19(b)(1) of the Act and Rule 19b–4 thereunder, seeking approval of changes to their Rules necessary to implement the proposal. 15 U.S.C. 78s(b)(1) and 17 CFR 240.19b–4, respectively. The proposed rule changes were published for comment in the **Federal Register** on June 20, 2017. Securities Exchange Act Release Nos. 80942 (June 15, 2017), 82 FR 28141 (June 20, 2017) (SR–NSCC–2017–007); 80941 (June 15, 2017), 82 FR 28207 (June 20, 2017) (SR–OCC–2017–013). The Commission received one comment letter to SR–OCC–2017–013. *See* letter from Pamela D. Marler, dated June 30, 2017. Such comment

receive any comments to the Advance Notices. This publication serves as notice that the Commission does not object to the changes set forth in the Advance Notices.

I. Description of the Advance Notices

The Advance Notices filed by the Clearing Agencies are a proposal to implement a new Stock Options and Futures Settlement Agreement (''New Accord'') between the Clearing Agencies, and to amend the Rules and Procedures of NSCC (''NSCC Rules'') and the By-Laws and Rules of OCC to accommodate the proposed provisions of the New Accord.[4]

Background

OCC issues and clears U.S.-listed options and futures on a number of underlying financial assets including common stocks, currencies and stock indices. OCC's Rules, however, provide that delivery of, and payment for, securities underlying certain physically settled stock options and single stock futures cleared by OCC are effected through the facilities of a correspondent clearing corporation (*i.e.,* NSCC) and are not settled through the facilities of OCC. To enable this arrangement concerning stock options, the Clearing Agencies currently are parties to a Third Amended and Restated Options Exercise Settlement Agreement, dated February 16, 1995, as amended (''Existing Accord''),[5] which governs the delivery and receipt of stock resulting from the exercise and assignment of stock options (*i.e.,* put and call options issued by OCC (''Stock Options'')). Pursuant to the Existing Accord, such stock must be: (i) Eligible for settlement through NSCC's Continuous Net Settlement (''CNS'') Accounting Operation and (ii) designated to settle on the third business day following the date the related exercise or assignment is accepted by NSCC (''Options E&A''), which is the current standard settlement cycle, known as ''regular way'' settlement.[6] All OCC Clearing Members that intend to engage in Stock Options transactions are required to also be Members of NSCC or to have appointed or nominated an NSCC Member to act on its behalf.[7]

The Advance Notices are a proposal by the Clearing Agencies to adopt a New Accord, which would provide for the settlement of the securities underlying certain Stock Options and delivery obligations arising from certain matured physically-settled single stock futures contracts cleared by OCC (''Stock Futures''). The New Accord would implement three major changes. First, the New Accord would expand the category of securities that would be eligible for settlement and guaranty under the agreement to certain securities (including stocks, exchange-traded funds and exchange-traded notes) that (i) are required to be delivered in the exercise and assignment of Stock Options and are eligible to be settled through NSCC's Balance Order Accounting Operation or (ii) are delivery obligations arising from Stock Futures that have reached maturity and are eligible to be settled through NSCC's CNS Accounting Operation or Balance Order Accounting Operation.[8] Second, the New Accord would modify the time of the transfer of responsibilities from OCC to NSCC and, specifically, when OCC's guarantee obligations under OCC's By-Laws and Rules with respect to such transactions (''OCC's Guaranty'') end and NSCC's obligations under Addendum K of the NSCC Rules with respect to such transactions (''NSCC's Guaranty'') begin, *i.e.,* when the ''Guaranty Substitution'' takes place. Third, the New Accord would put additional arrangements into place concerning the procedures, information sharing, and overall governance processes under the agreement. The Clearing Agencies propose to make certain clarifying and conforming changes to the NSCC Rules and the OCC By-Laws and Rules as necessary to implement the New Accord.

According to the Clearing Agencies, the primary purpose of the proposed changes is to: (1) Provide consistent treatment across all expiries for products with regular way[9] settlement cycle specifications; (2) reduce the operational complexities of the Existing Accord by delineating a single point in time at which OCC's Guaranty ceases and NSCC's Guaranty begins and clarifying the roles and responsibilities of the Clearing Agencies in the event of a default of a Common Member at either or both Clearing Agencies; and (3) improve procedures, information sharing, and overall governance under the agreement.

The New Accord would become effective, and wholly replace the Existing Accord, at a date specified in a service level agreement to be entered into between the Clearing Agencies.[10]

The Existing Accord

Key Terms of the Existing Accord

According to the Clearing Agencies, under the Existing Accord, the settlement of underlying securities resulting from Options E&A generally proceeds according to the following sequence of events. NSCC maintains and delivers to OCC a list (''CNS Eligibility Master File'') that enumerates all CNS Securities, which are defined in NSCC Rule 1 and generally include securities that have been designated by NSCC as eligible for processing through NSCC's CNS Accounting Operation and eligible for book entry delivery at NSCC's affiliate, The Depository Trust

letter does not specifically comment on any aspect of the proposed rule changes.

[4] Terms not defined herein are defined in the NSCC Rules, *available at http://www.dtcc.com/~/media/Files/Downloads/legal/rules/nscc_rules.pdf,* or in OCC's By-Laws and Rules, *available at http://optionsclearing.com/about/publications/bylaws.jsp,* as the context implies.

[5] The Existing Accord and the proposed changes thereunder were previously approved by the Commission. *See* Securities Exchange Act Release No. 37731 (September 26, 1996), 61 FR 51731 (October 3, 1996) (SR–OCC–96–04 and SR–NSCC–96–11) (Order Approving Proposed Rule Change Related to an Amended and Restated Options Exercise Settlement Agreement Between the Options Clearing Corporation and the National Securities Clearing Corporation); Securities Exchange Act Release No. 43837 (January 12, 2001), 66 FR 6726 (January 22, 2001) (SR–OCC–00–12) (Order Granting Accelerated Approval of a Proposed Rule Change Relating to the Creation of a Program to Relieve Strains on Clearing Members' Liquidity in Connection With Exercise Settlements); and Securities Exchange Act Release No. 58988 (November 20, 2008), 73 FR 72098 (November 26, 2008) (SR–OCC–2008–18 and SR–NSCC–2008–09) (Notice of Filing and Order Granting Accelerated Approval of Proposed Rule Changes Relating to Amendment No. 2 to the Third Amended and Restated Options Exercise Settlement Agreement).

[6] According to the Clearing Agencies, regular way settlement is understood to be the financial services industry's standard settlement cycle. Currently, regular way settlement of securities underlying Stock Options and stock futures takes place on the third business day following the date the related exercise, assignment or delivery obligation is accepted by NSCC. On or prior to September 5, 2017, the standard settlement cycle will be shortened to two business days after trade date, as required by the Commission. *See* Securities Exchange Act Release No. 80295 (March 22, 2017), 82 FR 15564 (March 29, 2017) (S7–22–16) (Securities Transaction Settlement Cycle). NSCC has amended its Rules with respect to the meaning of regular way settlement to be consistent with the shorter standard settlement cycle and will establish an effective date for these rule changes in a subsequent rule filing. *See* Securities Exchange Act Release No. 79734 (January 4, 2017), 82 FR 3030 (January 10, 2017) (SR–NSCC–2016–007).

[7] A firm that is both an OCC Clearing Member and an NSCC Member, or is an OCC Clearing Member that has designated an NSCC Member to act on its behalf is referred to herein as a ''Common Member.''

[8] The New Accord would continue to provide for the settlement of securities underlying Stock Options that settle through NSCC's CNS Accounting Operation.

[9] Under the New Accord, ''regular way settlement'' would have a meaning agreed to by the Clearing Agencies. This will address any changes to the standard settlement cycle. *See supra* note 6.

[10] Such effective date would be a date following approval of all required regulatory submissions to be filed by OCC and NSCC with the appropriate regulatory authorities, including these Advance Notices. *See supra* note 3.

Company (''CNS Eligible Securities'').[11] OCC, in turn, uses this file to make a final determination of which securities NSCC would not accept and therefore would need to be settled on a broker-to-broker basis. OCC then sends to NSCC a transactions file (''OCC Transactions File''),[12] listing the specific securities that are to be delivered and received as a result of Options E&A that have not previously been reported to NSCC and for which settlement is to be made through NSCC.[13] With respect to each Options E&A, the OCC Transactions File includes the CUSIP number of the security to be delivered, the identities of the delivering and receiving Common Members, the quantity to be delivered, the total value of the quantity to be delivered based on the exercise price of the option for which such security is the underlying security, and the exercise settlement date. After receiving the OCC Transactions File, NSCC then has until 11:00 a.m. Central Time on the following business day to reject any transaction listed in the OCC Transactions File. NSCC can reject a transaction if the security to be delivered has not been listed as a CNS Eligible Security in the CNS Eligibility Master File or if information provided in the OCC Transactions File is incomplete. Otherwise, if NSCC does not so notify OCC of its rejection of an Options E&A by the time required under the Existing Accord, NSCC will become unconditionally obligated to effect settlement of the underlying securities resulting from Options E&A.

According to the Clearing Agencies, under the Existing Accord, even after NSCC's trade guarantee has taken effect,[14] OCC retains its trade guarantee obligations with respect to the Options E&A until certain deadlines[15] have passed on the first business day following the scheduled settlement date. Once such deadlines have passed, OCC is released from its trade guarantee unless NSCC has notified OCC that the relevant Common Member has failed to meet an obligation to NSCC or NSCC has ceased to act for such Common Member pursuant to the NSCC Rules.[16] As a result, there is a period of time during which NSCC's trade guarantee overlaps with OCC's trade guarantee and for which both Clearing Agencies collect and hold margin from the Common Member.

In the event that NSCC or OCC ceases to act on behalf of or suspends a Common Member, that Common Member would become a ''defaulting member.'' Once a Common Member becomes a defaulting member, the Existing Accord provides that if OCC were to suspend a Common Member, NSCC would be required to make a payment to OCC equal to the lesser of OCC's total loss resulting from the closeout or the positive mark-to-market (''MTM'') amount relating to the defaulting member's Options E&A and that if NSCC were to suspend a Common Member, OCC would be required to make a payment to NSCC equal to the lesser of NSCC's total loss resulting from closeout or the negative mark-to-market amount relating to the defaulting member's Options E&A. A Clearing Agency must request the transfer of any such payments by the close of business on the tenth business day following the day of default and, after a request is made, the other Clearing Agency is required to make payment within five business days of the request.

The New Accord

Overview

As noted above, the Clearing Agencies propose to adopt a New Accord, which would provide for the settlement of certain securities underlying Stock Options and Stock Futures transactions. According to the Clearing Agencies, the New Accord is primarily designed to, among other things, expand the category of securities that are eligible for settlement and guaranty under the agreement; simplify the time of the transfer of responsibilities from OCC to NSCC (specifically, the Guaranty Substitution); and put additional arrangements into place concerning the procedures, information sharing, and overall governance processes under the agreement. The material provisions of the New Accord are described in detail below.

Key Elements of the New Accord

Expanded Scope of Eligible Securities

Pursuant to the proposed New Accord, on each day that both OCC and NSCC are open for accepting trades for clearing (''Activity Date''), NSCC would deliver to OCC an ''Eligibility Master File,'' which would identify the securities, including stocks, exchange-traded funds and exchange-traded notes, that are: (1) Eligible to settle through NSCC's CNS Accounting Operation (as is currently the case under the Existing Accord) or NSCC's Balance Order Accounting Operation (which is a feature of the New Accord) and (2) required to be physically delivered in settlement of (i) exercises and assignments of Stock Options (as is currently the case under the Existing Accord) or (ii) delivery obligations arising from maturing physically settled Stock Futures (which is a feature of the New Accord) (all such securities collectively being ''Eligible Securities''). OCC, in turn, would deliver to NSCC its file of E&A/Delivery Transactions[17] that list the Eligible Securities to be delivered, or received, and for which settlement is proposed to be made through NSCC on that Activity Date. Guaranty Substitution (discussed further below) would not occur with respect to an E&A/Delivery Transaction that is not submitted in the proper format or that involves a security that is not identified as an Eligible Security on the then-current Eligibility Master File. This process is similar to the current process under the Existing Accord with the exception of the expanded scope of Eligible Securities (and additional fields necessary to accommodate such securities) that would be listed on the Eligibility Master File and the E&A/Delivery Transactions file.

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[11] *Supra* note 4.

[12] According to the Clearing Agencies, delivery of the OCC Transactions File with respect to an Options E&A typically happens on the date of the option's exercise or expiration, though this is not expressly stated in the Existing Accord. However, in theory, an Options E&A could, due to an error or delay, be reported later than the date of the option's exercise or expiration.

[13] According to the Clearing Agencies, this process would be substantially the same under the New Accord with the exception that the CNS Eligibility Master File and OCC Transactions File would be renamed and would be expanded in scope to include additional securities that would be eligible for guaranty and settlement under the New Accord, as discussed in further detail below.

[14] Pursuant to Addendum K of the NSCC Rules, NSCC guarantees the completion of CNS transactions and balance order transactions that have reached the point at which, for bi-lateral submissions by Members, such trades have been validated and compared by NSCC, and for locked-in submissions, such trades have been validated by NSCC, as described in the NSCC Rules. Transactions that are covered by the Existing Accord, and that would be covered by the New Accord, are expressly excluded from the timeframes described in Addendum K. *See supra* note 4.

[15] The deadline is 6:00 a.m. Central Time for NSCC notifying OCC of a Common Member failure and, if NSCC does not immediately cease to act for such defaulting Common Member, 4:00 p.m. Central Time for notifying OCC that NSCC has ceased to act.

[16] *See* NSCC Rule 46 (Rule 46 (Restrictions on Access to Services). *See supra* note 4.

[17] ''E&A/Delivery Transactions'' are transactions involving the settlement of securities underlying Stock Options and Stock Futures under the New Accord. The delivery of E&A/Delivery Transactions to NSCC would replace the delivery of the ''OCC Transactions File'' from the Existing Accord. The actual information delivered by OCC to NSCC would be the same as is currently provided on the OCC Transactions File, but certain additional terms would be included to accommodate the inclusion of Stock Futures, along with information regarding the date that the instruction to NSCC was originally created and the E&A/Delivery Transaction's designated settlement date.

As with the Existing Accord, the proposed New Accord would continue to provide for the settlement of securities underlying Stock Options that settle through NSCC's CNS Accounting Operation and are designated to settle regular way. In addition, the New Accord would expand the category of securities eligible for settlement and guarantee by NSCC to include Stock Futures deliveries that are eligible to settle through NSCC's CNS Accounting Operation and are designated to settle regular way. The New Accord would also provide for the settlement of securities underlying both Stock Options and Stock Futures that are eligible to settle through NSCC's Balance Order Accounting Operation on a regular way basis. The primary purpose of expanding the category of securities that are eligible for settlement and guaranty under the agreement is to provide consistent treatment across all expiries for products with regular way settlement cycle specifications and simplify the settlement process for these additional securities transactions.

The New Accord would not apply to Stock Options or Stock Futures that are designated to settle on a shorter timeframe than the regular way settlement timeframe. These Stock Options would continue to be processed and settled as they would be today, outside of the New Accord. The New Accord also would not apply to any Stock Options or Stock Futures with underlying securities that are neither CNS Securities nor Balance Order Securities.[18] Transactions in these securities are, and would continue to be processed on a trade-for-trade basis away from NSCC's facilities. Such transactions may utilize other NSCC services for which they are eligible, but would not be subject to the New Accord.[19]

Proposed Changes Related to Guaranty Substitution

The New Accord would adopt a fundamentally different approach to the delineation of the rights and responsibilities of the Clearing Agencies with respect to Guaranty Substitution.

As described above, the Existing Accord provides that, following the default of a Common Member, and depending on the timing of the exercise or assignment guarantee, the Clearing Agency that suspends the Common Member will receive payment from the other Clearing Agency to compensate for potential losses incurred in connection with the Common Member's default. The proposed New Accord, in contrast, would clearly delineate a point in time at which OCC's Guaranty ends and NSCC's Guaranty begins (*i.e.,* the Guaranty Substitution takes place) with respect to E&A/Delivery Transactions. By focusing on the timing of the Guaranty Substitution, rather than payment from one Clearing Agency to the other, the New Accord would simplify the agreement and the procedures for situations involving the default of a Common Member. The New Accord additionally would minimize ''double-margining'' situations when a Common Member may simultaneously owe margin to both NSCC and OCC with respect to the same E&A/Delivery Transaction.

Under the New Accord, after NSCC has received an E&A/Delivery Transaction, the Guaranty Substitution would normally occur when NSCC has received all Required Deposits to its Clearing Fund, calculated taking into account such E&A/Delivery Transaction, of Common Members (''Guaranty Substitution Time'').[20] At the Guaranty Substitution Time, NSCC's Guaranty would take effect, and OCC would no longer retain any settlement obligations with respect to such E&A/Delivery Transactions.

The Guaranty Substitution would not occur, however, with respect to any E&A/Delivery Transaction if NSCC has rejected such E&A/Delivery Transaction due to an improper submission, as described above. The Guaranty Substitution also would not occur if, after NSCC's receipt of the E&A/Delivery Transaction but prior to receiving corresponding Clearing Fund deposits, a Common Member involved in the E&A/Delivery Transaction has defaulted on its obligations to NSCC by failing to meet its Clearing Fund obligations, or NSCC has otherwise ceased to act for such Common Member pursuant to the NSCC Rules (in either case, such Common Member becomes a ''Defaulting NSCC Member'').

NSCC would be required to promptly notify OCC if a Common Member becomes a Defaulting NSCC Member, as described above. Upon receiving such a notice, OCC would not submit to NSCC any additional E&A/Delivery Transactions involving the Defaulting NSCC Member for settlement, unless authorized representatives of both OCC and NSCC otherwise consent. OCC would, however, deliver to NSCC a list of all E&A/Delivery Transactions that have already been submitted to NSCC and that involve the Defaulting NSCC Member (''Defaulted NSCC Member Transactions''). The Guaranty Substitution would not occur with respect to such Defaulted NSCC Member Transactions, unless both Clearing Agencies agree otherwise. Therefore, NSCC would have no obligation to guarantee such Defaulted NSCC Member Transactions, and OCC would continue to be responsible for effecting the settlement of such Defaulted NSCC Member Transactions pursuant to OCC's By-Laws and Rules. Once NSCC has confirmed the list of Defaulted NSCC Member Transactions, Guaranty Substitution would occur for all submitted E&A/Delivery Transactions for that Activity Date that are not included on such list (*i.e.,* those transactions not involving the Defaulting NSCC Clearing Member). NSCC would be required to promptly notify OCC upon the occurrence of the Guaranty Substitution Time on each Activity Date.

If OCC suspends a Common Member after NSCC has received the E&A/Delivery Transactions but before the Guaranty Substitution has occurred, and that Common Member has not become a Defaulting NSCC Member, the Guaranty Substitution would proceed at the Guaranty Substitution Time. In such a scenario, OCC would continue to be responsible for guaranteeing the settlement of the E&A/Delivery Transactions in question until the Guaranty Substitution Time, at which time the responsibility would transfer to NSCC. If, however, the suspended Common Member also becomes a Defaulting NSCC Member after NSCC has received the E&A/Delivery Transactions but before the Guaranty Substitution has occurred, Guaranty Substitution would not occur, and OCC would continue to be responsible for effecting the settlement of such Defaulted NSCC Member Transactions pursuant to OCC's By-Laws and Rules (unless both Clearing Agencies agree otherwise).

Finally, the New Accord also would provide for the consistent treatment of all exercise and assignment activity under the agreement. Under the Existing Accord, ''standard'' [21] option contracts

[18] Balance Order Securities are defined in NSCC Rule 1, and are generally securities, other than foreign securities, that are eligible to be cleared at NSCC but are not eligible for processing through the CNS Accounting Operation. *See supra* note 4.

[19] OCC will continue to guarantee settlement until settlement actually occurs with respect to these Stock Options and Stock Futures.

[20] Procedure XV of the NSCC Rules provides that all Clearing Fund requirements and other deposits be made within one hour of demand, unless NSCC determines otherwise. *See supra* note 4.

[21] Option contracts with ''standard'' expirations expire on the third Friday of the specified

Continued

become guaranteed by NSCC when the Common Member meets its morning Clearing Fund Required Deposit at NSCC while ''non-standard'' exercise and assignment activity becomes guaranteed by NSCC at midnight of the day after trade date (T+1). Under the New Accord, all exercise and assignment activity for Eligible Securities would be guaranteed by NSCC as of the Guaranty Substitution Time, under the circumstances described above, further simplifying the framework for the settlement of such contracts.

Other Terms of the New Accord

The New Accord would include a number of other provisions intended to maintain certain terms of the Existing Accord or improve the procedures, information sharing, and overall governance process under the new agreement. Many of these terms are additions to or improvements upon the terms of the Existing Accord.

Under the proposed New Accord, the Clearing Agencies would agree to address the specifics regarding the time, form, and manner of various required notifications and actions in a separate service level agreement, which the parties would be able to revisit as their operational needs evolve. The separate service level agreement also would specify an effective date for the New Accord, which would occur on a date following approval and effectiveness of all required regulatory submissions to be filed by OCC and NSCC with the appropriate regulatory authorities. Similar to the Existing Accord, the proposed New Accord would remain in effect: (a) Until it is terminated by the mutual written agreement of OCC and NSCC; (b) until it is unilaterally terminated by either Clearing Agency upon one year's written notice (as opposed to six months under the Existing Accord); or (c) until it is terminated by either NSCC or OCC upon the bankruptcy or insolvency of the other, provided that the election to terminate is communicated to the other party within three business days by written notice.

Under the proposed New Accord, NSCC would agree to notify OCC if NSCC ceases to act for a Common Member pursuant to the NSCC Rules no later than the earlier of NSCC's provision of notice of such action to the governmental authorities or notice to other NSCC Members. Furthermore, if an NSCC Member for which NSCC has not yet ceased to act fails to satisfy its Clearing Fund obligations to NSCC, NSCC would be required to notify OCC promptly after discovery of the failure. Likewise, OCC would be required to notify NSCC of the suspension of a Common Member no later than the earlier of OCC's provision of notice to the governmental authorities or other OCC Clearing Members.

Under the Existing Accord, NSCC and OCC agree to share certain reports and information regarding settlement activity and obligations under the agreement. The New Accord would enhance this information sharing between the Clearing Agencies. For example, the Clearing Agencies would agree to share certain information, including general risk management due diligence regarding Common Members, lists of Common Members, and information regarding margin and settlement obligations of the Common Members. The Clearing Agencies would also agree to provide each other with any other information that the other reasonably requests in connection with their obligations under the New Accord. All such information would be required to be kept confidential, using the same care and discretion that each Clearing Agency uses for the safekeeping of its own members' confidential information. NSCC and OCC would each be required to act in good faith to resolve and notify the other of any errors, discrepancies or delays in the information it provides.

The New Accord also would include new terms to provide that, to the extent a Clearing Agency is unable to perform any obligation as a result of the failure of the other Clearing Agency to perform its responsibilities on a timely basis, the time for the non-failing Clearing Agency's performance would be extended, its performance would be reduced to the extent of any such impairment, and it would not be liable for any failure to perform its obligations. Further, NSCC and OCC would agree that neither Clearing Agency would be liable to the other Clearing Agency in connection with its performance of its obligations under the proposed New Accord to the extent it has acted, or omitted or ceased to act, with the permission or at the direction of a governmental authority. Moreover, the proposed New Accord would provide that in no case would either Clearing Agency be liable to the other for punitive, incidental or consequential damages. The purpose of these new provisions is to provide clear and specific terms regarding each Clearing Agency's liability for non-performance under the agreement.

The proposed New Accord would also contain the usual and customary representations and warranties for an agreement of this type, including representations as to the parties' good standing, corporate power and authority and operational capability, that the agreement complies with laws and all government documents and does not violate any agreements, and that all of the required regulatory notifications and filings would be obtained prior to the New Accord's effective date. It would also include representations that the proposed New Accord constitutes a legal, valid and binding obligation on each of OCC and NSCC and is enforceable against each, subject to standard exceptions. Furthermore, the proposed New Accord would contain a force majeure provision, under which NSCC and OCC would agree to notify the other no later than two hours upon learning that a force majeure event has occurred and both parties would be required to cooperate in good faith to mitigate the effects of any resulting inability to perform or delay in performing.

Proposed Amendments to NSCC Rules

Given the key differences between the Existing Accord and the New Accord, as described above, NSCC proposes certain changes to Procedures III and XV of the NSCC Rules to accommodate the terms of the New Accord. In particular, NSCC would update Section B of Procedure III to define the scope of the New Accord. First, the proposed Section B of Procedure III would identify the E&A/Delivery Transactions, and would make clear that the New Accord would apply only to E&A/Delivery Transactions that are in either CNS Securities or Balance Order Securities, as such terms are defined in the NSCC Rules. The proposed Section B of Procedure III would also define the Common Members, or firms that must be named as counterparties to E&A/Delivery Transactions, as ''Participating Members.'' The proposal would describe the Guaranty Substitution Time and would describe the circumstances under which the Guaranty Substitution would not occur. Finally, the proposed Section B of Procedure III would describe how E&A/Delivery Transactions for which the Guaranty Substitution has occurred would be processed at NSCC both if they are covered by the proposed New Accord and if they are not covered by the proposed New Accord because, for example, they are not transactions in CNS Securities or Balance Order Securities or were not submitted for regular way settlement.

Finally, NSCC is also proposing to amend Procedure XV to remove

expiration month, while ''non-standard'' contracts expire on other days of the expiration month.

reference to the exclusion of E&A/Delivery Transactions from the calculation of the mark-to-market margin component of its Clearing Fund calculations, which is no longer applicable under the proposed New Accord where the Guaranty Substitution would replace the transfer of a defaulting Common Member's margin payments under the Existing Accord. Therefore, NSCC is not proposing any change to its margining methodology, but will include E&A/Delivery Transactions in the calculation of the mark-to-market margin component of Common Members' Clearing Fund Required Deposits following implementation of the New Accord.

Proposed Amendments to OCC's By-Laws and Rules

OCC also proposes certain changes to its By-Laws and Rules to accommodate the terms of the New Accord. The primary purpose of the proposed changes is to: (1) Reflect the expanded scope of the New Accord, (2) reflect changes related to the new Guaranty Substitution mechanics of the New Accord; and (3) make other changes necessary to conform to the terms of the New Accord or to otherwise provide additional clarity around the settlement and margining [22] treatment of: (i) Eligible Securities under the New Accord, (ii) non-regular way securities settling through the facilities of NSCC but outside of the New Accord, and (iii) those securities settling outside of the New Accord and away from NSCC on a broker-to-broker basis. These proposed changes are discussed in greater detail below.

Changes Related to the Expanded Scope of the New Accord

First, OCC proposes to amend and replace the defined term ''CNS-eligible'' [23] to reflect the expanded definition of Eligible Securities under the New Accord. The term ''CNS-eligible'' currently describes the securities underlying the physically-settled stock options that are eligible under the Existing Accord to be settled through NSCC's CNS Accounting Operation. Under the New Accord, however, the term Eligible Securities is more broadly defined to include securities (both Stock Options and Stock Futures) eligible for settlement via NSCC's CNS Accounting Operation and NSCC's Balance Order Accounting Operation. Accordingly, OCC proposes to use ''CCC,'' for ''correspondent clearing corporation'' [24] to describe the Eligible Securities. Thus, the term ''CCC-eligible'' would replace ''CNS-eligible'' throughout OCC's By-Laws and Rules.

Next, because the New Accord would include the settlement of securities underlying Stock Futures, OCC proposes to make several changes to its rules regarding Stock Futures to accommodate this expansion. More specifically, OCC proposes a conforming amendment to Rule 901 Interpretation and Policy (.02) to clarify that, under the New Accord, OCC will, subject to its discretion, cause the settlement of all matured Stock Futures to be made through the facilities of NSCC to the extent that the underlying securities are CCC-eligible as the term is currently proposed.

OCC also proposes clarifying and conforming revisions to newly renumbered Rule 901(e) (currently Rule 901(d)) to specify that settlements made through the facilities of the correspondent clearing corporation are governed by Rule 901 and to clarify that, under the New Accord, specifications made in any Delivery Advice may be revoked up until the point at which NSCC's Guaranty has taken effect (the ''obligation time'' as discussed below) and not the opening of business on the delivery date.

Changes Related to Guaranty Substitution

OCC also proposes a series of amendments to its Rules to accurately reflect the process under which the Guaranty Substitution occurs under the New Accord. First, OCC proposes to amend Rule 901(c) so that the term ''obligation time''—the time that the correspondent clearing corporation becomes unconditionally obligated, in accordance with its rules, to effect settlement in respect thereof or to close out the securities contract arising therefrom—is synonymous with the Guaranty Substitution Time under the New Accord (*i.e.,* (i) settlement obligations are reported to and are not rejected by NSCC; (ii) NSCC has not notified OCC that NSCC has ceased to act for the relevant Clearing Member; and (iii) the Clearing Fund requirements of the relevant Clearing Member are received by NSCC). Under the New Accord, if a default occurs prior to the Guaranty Substitution Time, the Guaranty Substitution will not occur for any E&A/Delivery Transactions involving the Defaulting NSCC Member, and OCC will continue to guarantee settlement for those Defaulted NSCC Member Transactions.

Next, OCC proposes to amend language in newly renumbered Rule 901(i) (currently Rule 901(h)) regarding the timing of the end of a Clearing Member's obligations to OCC with respect to securities to be settled through NSCC. Under the Existing Accord and OCC's existing Rules, a Clearing Member's obligations to OCC end only once settlement is completed. Under the New Accord, however, a Clearing Member's obligations to OCC will end when OCC's obligations with respect to guaranteeing settlement of the security would end (*i.e.,* the Guaranty Substitution Time or ''obligation time''). OCC therefore proposes to amend newly renumbered Rule 901(i) to specify that a Clearing Member's obligations to OCC will be deemed completed and performed once the ''obligation time'' has occurred.

As discussed above, the New Accord eliminates the provisions of the Existing Accord whereby OCC and NSCC guaranteed each other the performance of Common Members and made certain payments to the other upon the default of a Common Member. Therefore, OCC proposes to delete discussions of such guarantees and payments from newly renumbered Rule 901(i) and Rule 1107.

OCC also proposes amendments to Rules 910 and 911, which set forth procedures for handling failures to make or take delivery of securities in settlement of exercised or assigned Stock Options and matured physically-settled Stock Futures, to add language to both rules to clarify that the failure procedures set forth therein would not apply with respect to any delivery to be made through NSCC pursuant to Rule 901. Under the New Accord, once the Guaranty Substitution Time with respect to a specific E&A/Delivery Transaction occurs, OCC's Guaranty ends and NSCC's Guaranty begins, leaving OCC with no involvement with or responsibility for the settlement of the securities underlying that transaction. Therefore, if there is a failure to make or take delivery with respect to that transaction after Guaranty Substitution has occurred, the

[22] OCC notes that, while it is proposing changes to its Rules concerning margin requirements (*e.g.,* which transactions would be included as part of OCC's margin calculation at a given point in time), OCC is not proposing any changes to its margin model (with the exception that OCC would no longer collect and hold margin for positions after NSCC's Guaranty has taken effect under the New Accord).

[23] *See* Article I, Section (C)(23) of OCC's By-Laws.

[24] Under Article I of OCC's By-Laws, the term ''correspondent clearing corporation'' means the National Securities Clearing Corporation or any successor thereto which, by agreement with the Corporation, provides facilities for settlements in respect of exercised option contracts or BOUNDs (*i.e.,* securities issued by OCC pursuant to Article XXIV of OCC's By-Laws and Chapter XXV of OCC's Rules) or in respect of delivery obligations arising from physically-settled stock futures. *See supra* note 4.

NSCC Rules will govern that failure. With respect to deliveries made on a broker-to-broker basis under OCC Rules 903 through 912 (including those that may utilize NSCC's Obligation Warehouse services), and which are not governed by Rule 901, Guaranty Substitution does not occur and OCC's failure procedures would apply.

Changes to OCC's Margin Rules

Under the New Accord, OCC will no longer collect margin on a transaction once it is no longer guaranteeing settlement for that transaction. Therefore, OCC proposes to add language to Rule 601(f) to clarify that OCC's margin calculations will not include delivery obligations arising from any Stock Options or Stock Futures that are eligible for settlement through NSCC and for which OCC has no further settlement obligations because either (i) Guaranty Substitution has occurred for E&A/Delivery Transactions under the New Accord (as described in revised Rule 901(c)) or (ii) NSCC has otherwise accepted transactions for non-regular way settlement under the NSCC Rules (as describe in newly proposed Rule 901(d)).[25] By not including these transactions as part of OCC's margin calculation, OCC is hoping to alleviate instances of ''double-margining'' for Common Members that may otherwise simultaneously owe margin to NSCC and OCC with respect to the same position.

OCC also proposes to delete Rule 608A in its entirety. The New Accord seeks to eliminate the situation under the Existing Accord where Common Members are effectively ''double-margined'' or required to simultaneously post margin with OCC and NSCC with respect to the same position. As the New Accord eliminates this double-margining scenario, Rule 608A, which provides procedures pursuant to which a Clearing Member could use the securities deposited as margin with OCC as collateral to secure a loan to pay its margin obligations to NSCC, is now unnecessary.

Other Clarifying Changes Not Related to the New Accord

OCC also proposes to amend its Rules to make clarifying changes that are not directly required by the New Accord but would provide additional clarity in its Rules in light of other changes being made to accommodate the New Accord. Specifically, OCC proposes to revise Rule 901 Interpretation and Policy (.02) to provide that transactions that involve the delivery of non-CCC eligible securities made on a broker-to-broker basis (and away from NSCC) may nevertheless involve the use of certain services of NSCC (*e.g.,* NSCC's Obligation Warehouse). For such transactions, because they are not covered by the New Accord and NSCC at no point guarantees settlement, OCC Rule 901 would not apply and delivery is governed by the broker-to-broker settlement procedures set forth in OCC Rules 903 through 912, as is the case currently today. Additionally, while OCC's existing Rules do not prohibit broker-to-broker settlements from being facilitated through the services of a correspondent clearing corporation, they do not explicitly contemplate the possibility. OCC also proposes to make clarifying amendments to Rule 904(b) and 910A(a) to more clearly distinguish between settlements effected through NSCC's CNS Accounting Operation or Balance Order Accounting Operations in accordance with OCC Rule 901 and deliveries effected on a broker-to-broker basis utilizing services of NSCC under OCC Rules 903 through 912 and to clearly state which OCC Rules apply in each context.

Further, OCC proposes to add a new paragraph (d) to Rule 901 to clarify that OCC still intends, at its discretion, to effect settlement of Stock Options and Stock Futures that are scheduled to be settled on the first business day after exercise or maturity through NSCC pursuant to Rule 901 and the relevant provisions of the NSCC Rules, even though such contracts are outside the scope of the New Accord. These contracts would continue to be settled as they are currently today.

OCC also proposes clarifying and conforming changes to the introductory language of Chapter IX of the Rules. Specifically, OCC proposes conforming changes to the Rule to reflect the replacement of the defined term ''CNS-eligible'' with ''CCC-eligible'' as described above. The proposed changes would also clarify that OCC's broker-to-broker settlement rules are contained in Rules 903–912, as Rule 902 concerns Delivery Advices, which also may be applicable to settlements made through the correspondent clearing corporation pursuant to Rule 901. In addition, the proposed changes to the introductory language of Chapter IX of the Rules would provide additional clarity around OCC's existing authority to alter a previous designation of a settlement method at any time prior to the designated delivery date by specifying that this authority would apply to both settlements to be made through the facilities of the correspondent clearing corporation pursuant to Rule 901 or settlements to be made on a broker-to-broker basis pursuant to Rules 903 through 912. Finally, OCC proposes a number of conforming changes to Rules 901 and 912 to reflect the renumbering of various Rule provisions due to the proposed amendments described above.

II. Discussion and Commission Findings

Although the Clearing Supervision Act does not specify a standard of review for an advance notice, its stated purpose is instructive: To mitigate systemic risk in the financial system and promote financial stability by, among other things, promoting uniform risk management standards for systemically important financial market utilities and strengthening the liquidity of systemically important financial market utilities.[26]

Section 805(a)(2) of the Clearing Supervision Act[27] authorizes the Commission to prescribe risk management standards for the payment, clearing and settlement activities of designated clearing entities engaged in designated activities for which the Commission is the supervisory agency. Section 805(b) of the Clearing Supervision Act[28] provides the following objectives and principles for the Commission's risk management standards prescribed under Section 805(a):

- To promote robust risk management;
- to promote safety and soundness;
- to reduce systemic risks; and
- to support the stability of the broader financial system.

The Commission has adopted risk management standards under Section 805(a)(2) of the Clearing Supervision Act[29] and Section 17A of the Act (''Rule 17Ad–22'').[30] Rule 17Ad–22 requires registered clearing agencies to establish, implement, maintain, and enforce written policies and procedures that are reasonably designed to meet certain minimum requirements for their operations and risk management practices on an ongoing basis.[31] Therefore, it is appropriate for the Commission to review proposed changes in advance notices against the objectives and principles of these risk management standards as described in

[25] Related revisions to Rule 901(c) and newly proposed Rule 901(d) are discussed in more detail below.

[26] 12 U.S.C. 5461(b).

[27] 12 U.S.C. 5464(a)(2).

[28] 12 U.S.C. 5464(b).

[29] 12 U.S.C. 5464(a)(2).

[30] *See* 17 CFR 240.17Ad–22.

[31] *Id.*

Section 805(b) of the Clearing Supervision Act and against Rule 17Ad–22.[32]

A. Consistency With Section 805(b) of the Clearing Supervision Act

The Commission believes that the changes proposed in the Advance Notices are consistent with Section 805(b) of the Clearing Supervision Act[33] because they are designed to reduce systemic risk and to promote robust risk management by mitigating operational risk.

The proposal would expand the category of securities eligible for settlement and guarantee under the New Accord to include Stock Futures deliveries that are eligible to settle through NSCC's CNS Accounting Operation, as well as securities underlying Stock Options and Stock Futures that are eligible to settle through NSCC's Balance Order Accounting Operation, where each are scheduled to settle regular way. By including these additional securities as part of the New Accord, the proposal would provide for more uniform settlement processing of securities with regular way settlement. According to the Clearing Agencies, the expansion of the category of securities eligible for settlement and guarantee under the New Accord would simplify the settlement process for these additional securities transactions. By providing for more uniform settlement processing, simplifying the settlement process, and subjecting such transactions to enhanced information sharing and governance, as described below, this change is intended to promote robust risk management by mitigating operational risk.

The proposal would establish additional arrangements concerning the procedures, information sharing, and overall governance processes under the New Accord. For example, the Clearing Agencies would agree to share certain information, including general risk management due diligence regarding Common Members, lists of Common Members, and information regarding margin and settlement obligations of the Common Members. The Clearing Agencies also would agree to provide each other with any other information that the other reasonably requests in connection with their obligations under the New Accord. Such agreements are designed to help the Clearing Agencies to more effectively identify, monitor, and manage risks that may be presented by certain Common Members.

The New Accord also would establish the Guaranty Substitution Time (*i.e.,* a specific point in time where trade guarantee obligations would transfer from OCC to NSCC), with respect to the applicable securities transactions, as described above. The Guaranty Substitution Time would help eliminate ambiguity and complexity that exists in the current guarantee practice regarding which Clearing Agency is responsible for guaranteeing settlement at any given moment, and help provide greater certainty that, in the event of the default of a Common Member, the default would be handled pursuant to the rules and procedures of the Clearing Agency whose guarantee is then in effect. This proposed change is designed to help strengthen the Clearing Agencies' abilities to plan for, manage, and, therefore, mitigate the risks that the default of a Common Member could present to the Clearing Agencies, other clearing members, and the market as a whole.

By assisting the Clearing Agencies with mitigating operational risk, as well as more effectively managing risks presented by certain Common Members, including the risk presented by Common Member defaults, the proposed changes are designed to reduce systemic risk and promote robust risk management. Therefore, the Commission believes that the changes proposed in the Advance Notices are consistent with Section 805(b) of the Clearing Supervision Act.[34]

B. Consistency With Rule 17Ad–22(e)(20)

The Commission believes that the changes proposed in the Advance Notices are consistent with Rule 17Ad–22(e)(20) under the Act, which requires, in part, that the Clearing Agencies establish, implement, maintain and enforce written policies and procedures reasonably designed to identify, monitor, and manage risks related to any link the clearing agency establishes with one or more other clearing agencies.[35]

Under the terms of the Existing Accord, even after NSCC's trade guarantee has taken effect, OCC is not released from its trade guarantee with respect to the transactions until certain deadlines have passed, as discussed above. As a result, the Existing Accord creates a complicated framework for the settlement of securities underlying certain Stock Options, which could lead to an unanticipated disruption to the Clearing Agencies' respective clearing operations.

The New Accord is designed to better mitigate and manage the risks related to the link the Clearing Agencies have established with each other to settle the securities underlying Stock Options and Stock Futures. For example, by instituting the Guaranty Substitution Time, the New Accord would provide for a clearer, simpler framework for the settlement of securities underlying certain Stock Options and Stock Futures by setting a specific time at which trade guarantee obligations would transfer from OCC to NSCC. This would help eliminate the ambiguity that currently exists regarding which Clearing Agency is responsible for guaranteeing settlement at any given moment. It would also provide greater certainty that in the event of a Common Member default, the default would be handled pursuant to the rules and procedures of the Clearing Agency whose guarantee is then in effect. This greater certainty, in turn, is designed to help improve the OCC's and NSCC's ability to plan for and manage the risk presented by the default of a Common Member, and the effects that such a default could have on other members and the markets the Clearing Agencies serve.

In connection with the proposal to put additional arrangements into place concerning the procedures, information sharing, and overall governance processes under the New Accord, the Clearing Agencies would agree to share certain information, including general surveillance information regarding their members. Such arrangements are designed to help each Clearing Agency more effectively identify, monitor, and manage risks that may be presented by Common Members.

For the above reasons, the Commission believes that the New Accord is designed to assist the Clearing Agencies in identifying, monitoring, and managing risks related to the link between the Clearing Agencies. Therefore, the Commission believes that the changes proposed in the Advance Notices are consistent with Rule 17Ad–22(e)(20).[36]

C. Consistency With Rule 17Ad–22(e)(21)

The Commission believes that the proposal is consistent with Rule 17Ad–22(e)(21) under the Act, which requires, in part, that the Clearing Agencies establish, implement, maintain and enforce written policies and procedures reasonably designed to be efficient and effective in meeting the requirements of

[32] 12 U.S.C. 5464(b).

[33] *Id.*

[34] *Id.*

[35] 17 CFR 240.17Ad–22(e)(20).

[36] *Id.*

its participants and the markets it serves.[37] As described above, the proposal would modify the timing of the Guaranty Substitution by establishing the Guaranty Substitution Time. In doing so, the New Accord would minimize the ''double margining'' issue [38] that is present under the Existing Accord. As a result, Common Members would no longer be required to post margin at both Clearing Agencies to cover the same transactions. By simplifying the terms of the existing agreement in this way, the New Accord is designed to be more efficient and effective in meeting the requirements of OCC's and NSCC's participants and the markets they serve.

Furthermore, as described above, the proposed changes would establish additional arrangements between the Clearing Agencies concerning the procedures, information sharing, and overall governance processes under the New Accord. Such arrangements could enhance information sharing between the Clearing Agencies and enable them to more effectively identify, monitor, and manage risks that may be presented by certain Common Members.

Because the New Accord would allow for greater information sharing and eliminate the need for Common Members to post margin at both Clearing Agencies for the same transactions, the Commission believes the proposal is designed to be efficient and effective in meeting the requirements of Common Members. Therefore, the Commission believes that the changes proposed in the Advance Notices are consistent with the requirements of Rule 17Ad–22(e)(21).[39]

III. Conclusion

It is therefore noticed, pursuant to Section 806(e)(1)(I) of the Clearing Supervision Act,[40] that the Commission *does not object* to these advance notice proposals (SR–NSCC–2017–803 and SR–OCC–2017–804) and that the Clearing Agencies are *authorized* to implement the proposals as of the date of this notice or the date of an order by the Commission approving a proposed rule change that reflects rule changes that are consistent with the relevant advance notice proposal (SR–NSCC–2017–007, SR–OCC–2017–013), whichever is later.

By the Commission.

Eduardo A. Aleman,

Assistant Secretary.

[FR Doc. 2017–16395 Filed 8–3–17; 8:45 am]

BILLING CODE 8011–01–P

[37] 17 CFR 240.17Ad–22(e)(21).

[38] As noted above, under the Existing Accord, even after NSCC's trade guarantee has taken effect, OCC retains its trade guarantee obligations with respect to the options exercise or assignment until certain deadlines have passed on the first business day following the scheduled settlement date. Once such deadlines have passed, OCC is released from its trade guarantee unless NSCC has notified OCC that the relevant Common Member has failed to meet an obligation to NSCC or NSCC has ceased to act for such firm. This results in a period of time during which NSCC's trade guarantee overlaps with OCC's trade guarantee, for which both Clearing Agencies collect and hold margin from the Common Member. *See supra* note 15.

[39] 17 CFR 240.17Ad–22(e)(21).

[40] 12 U.S.C. 5465(e)(1)(I).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–81266; File Nos. SR–NSCC–2017–007; SR–OCC–2017–013]

Self-Regulatory Organizations; National Securities Clearing Corporation; The Options Clearing Corporation; Order Approving Proposed Rule Changes Concerning the Adoption of a New Stock Options and Futures Settlement Agreement Between the National Securities Clearing Corporation and The Options Clearing Corporation

July 31, 2017.

On June 1, 2017, National Securities Clearing Corporation (''NSCC'') and The Options Clearing Corporation (''OCC,'' each a ''Clearing Agency,'' and collectively, ''Clearing Agencies'') filed with the Securities and Exchange Commission (''Commission'') proposed rule changes SR–NSCC–2017–007 and SR–OCC–2017–013 respectively (collectively, the ''Proposed Rule Changes''), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder.[2] The Proposed Rule Changes were published for comment in the **Federal Register** on June 20, 2017.[3] The Commission received one comment letter to SR–OCC–2017–013.[4] This order approves the Proposed Rule Changes.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] Securities Exchange Act Release Nos. 80942 (June 15, 2017), 82 FR 28141 (June 20, 2017) (SR–NSCC–2017–007); 80941 (June 15, 2017), 82 FR 28207 (June 20, 2017) (SR–OCC–2017–013). The Clearing Agencies also filed the Proposed Rule Changes as advance notices pursuant to Section 806(e)(1) of the Payment, Clearing, and Settlement Supervision Act of 2010 and Rule 19b–4(n)(1) under the Act. 15 U.S.C. 5465(e)(1) and 17 CFR 240.19b–4(n)(1). The advance notices were published for comment in the **Federal Register** on July 5, 2017. *See* Securities Exchange Act Release Nos. 81039 (June 28, 2017), 82 FR 31123 (July 5, 2017) (SR–NSCC–2017–803); 81040 (June 28, 2017), 82 FR 31109 (July 5, 2017) (SR–OCC–2017–804). The Commission did not receive any comments on the advance notices.

[4] *See* letter from Pamela D. Marler, dated June 30, 2017. Such comment letter does not specifically comment on any aspect of the Proposed Rule Changes.

I. Description of the Proposed Rule Changes

The Proposed Rule Changes filed by the Clearing Agencies are a proposal to implement a new Stock Options and Futures Settlement Agreement (''New Accord'') between the Clearing Agencies, and to amend the Rules and Procedures of NSCC (''NSCC Rules'') and the By-Laws and Rules of OCC to accommodate the proposed provisions of the New Accord.[5]

Background

OCC issues and clears U.S.-listed options and futures on a number of underlying financial assets including common stocks, currencies and stock indices. OCC's Rules, however, provide that delivery of, and payment for, securities underlying certain physically settled stock options and single stock futures cleared by OCC are effected through the facilities of a correspondent clearing corporation (*i.e.,* NSCC) and are not settled through the facilities of OCC. To enable this arrangement concerning stock options, the Clearing Agencies currently are parties to a Third Amended and Restated Options Exercise Settlement Agreement, dated February 16, 1995, as amended (''Existing Accord''),[6] which governs the delivery and receipt of stock resulting from the exercise and assignment of stock options (*i.e.,* put and call options issued by OCC (''Stock Options'')). Pursuant to the Existing Accord, such stock must be: (i) Eligible for settlement through NSCC's Continuous Net Settlement (''CNS'') Accounting Operation and (ii) designated to settle

[5] Terms not defined herein are defined in the NSCC Rules, *available at http://www.dtcc.com/~/media/Files/Downloads/legal/rules/nscc_rules.pdf,* or in OCC's By-Laws and Rules, *available at http://optionsclearing.com/about/publications/bylaws.jsp,* as the context implies.

[6] The Existing Accord and the proposed changes thereunder were previously approved by the Commission. *See* Securities Exchange Act Release No. 37731 (September 26, 1996), 61 FR 51731 (October 3, 1996) (SR–OCC–96–04 and SR–NSCC–96–11) (Order Approving Proposed Rule Change Related to an Amended and Restated Options Exercise Settlement Agreement Between the Options Clearing Corporation and the National Securities Clearing Corporation); Securities Exchange Act Release No. 43837 (January 12, 2001), 66 FR 6726 (January 22, 2001) (SR–OCC–00–12) (Order Granting Accelerated Approval of a Proposed Rule Change Relating to the Creation of a Program to Relieve Strains on Clearing Members' Liquidity in Connection With Exercise Settlements); and Securities Exchange Act Release No. 58988 (November 20, 2008), 73 FR 72098 (November 26, 2008) (SR–OCC–2008–18 and SR–NSCC–2008–09) (Notice of Filing and Order Granting Accelerated Approval of Proposed Rule Changes Relating to Amendment No. 2 to the Third Amended and Restated Options Exercise Settlement Agreement).

on the third business day following the date the related exercise or assignment is accepted by NSCC (''Options E&A''), which is the current standard settlement cycle, known as ''regular way'' settlement.[7] All OCC Clearing Members that intend to engage in Stock Options transactions are required to also be Members of NSCC or to have appointed or nominated an NSCC Member to act on its behalf.[8]

The Proposed Rule Changes are a proposal by the Clearing Agencies to adopt a New Accord, which would provide for the settlement of the securities underlying certain Stock Options and delivery obligations arising from certain matured physically-settled single stock futures contracts cleared by OCC (''Stock Futures''). The New Accord would implement three major changes. First, the New Accord would expand the category of securities that would be eligible for settlement and guaranty under the agreement to certain securities (including stocks, exchange-traded funds and exchange-traded notes) that (i) are required to be delivered in the exercise and assignment of Stock Options and are eligible to be settled through NSCC's Balance Order Accounting Operation or (ii) are delivery obligations arising from Stock Futures that have reached maturity and are eligible to be settled through NSCC's CNS Accounting Operation or Balance Order Accounting Operation.[9] Second, the New Accord would modify the time of the transfer of responsibilities from OCC to NSCC and, specifically, when OCC's guarantee obligations under OCC's By-Laws and Rules with respect to such transactions (''OCC's Guaranty'') end and NSCC's obligations under Addendum K of the NSCC Rules with respect to such transactions (''NSCC's Guaranty'') begin, *i.e.,* when the ''Guaranty Substitution'' takes place. Third, the New Accord would put additional arrangements into place concerning the procedures, information sharing, and overall governance processes under the agreement. The Clearing Agencies propose to make certain clarifying and conforming changes to the NSCC Rules and the OCC By-Laws and Rules as necessary to implement the New Accord.

According to the Clearing Agencies, the primary purpose of the proposed changes is to: (1) Provide consistent treatment across all expiries for products with regular way [10] settlement cycle specifications; (2) reduce the operational complexities of the Existing Accord by delineating a single point in time at which OCC's Guaranty ceases and NSCC's Guaranty begins and clarifying the roles and responsibilities of the Clearing Agencies in the event of a default of a Common Member at either or both Clearing Agencies; and (3) improve procedures, information sharing, and overall governance under the agreement.

The New Accord would become effective, and wholly replace the Existing Accord, at a date specified in a service level agreement to be entered into between the Clearing Agencies.[11]

The Existing Accord

Key Terms of the Existing Accord

According to the Clearing Agencies, under the Existing Accord, the settlement of underlying securities resulting from Options E&A generally proceeds according to the following sequence of events. NSCC maintains and delivers to OCC a list (''CNS Eligibility Master File'') that enumerates all CNS Securities, which are defined in NSCC Rule 1 and generally include securities that have been designated by NSCC as eligible for processing through NSCC's CNS Accounting Operation and eligible for book entry delivery at NSCC's affiliate, The Depository Trust Company (''CNS Eligible Securities'').[12] OCC, in turn, uses this file to make a final determination of which securities NSCC would not accept and therefore would need to be settled on a broker-to-broker basis. OCC then sends to NSCC a transactions file (''OCC Transactions File''),[13] listing the specific securities that are to be delivered and received as a result of Options E&A that have not previously been reported to NSCC and for which settlement is to be made through NSCC.[14] With respect to each Options E&A, the OCC Transactions File includes the CUSIP number of the security to be delivered, the identities of the delivering and receiving Common Members, the quantity to be delivered, the total value of the quantity to be delivered based on the exercise price of the option for which such security is the underlying security, and the exercise settlement date. After receiving the OCC Transactions File, NSCC then has until 11:00 a.m. Central Time on the following business day to reject any transaction listed in the OCC Transactions File. NSCC can reject a transaction if the security to be delivered has not been listed as a CNS Eligible Security in the CNS Eligibility Master File or if information provided in the OCC Transactions File is incomplete. Otherwise, if NSCC does not so notify OCC of its rejection of an Options E&A by the time required under the Existing Accord, NSCC will become unconditionally obligated to effect settlement of the underlying securities resulting from Options E&A.

According to the Clearing Agencies, under the Existing Accord, even after NSCC's trade guarantee has taken effect,[15] OCC retains its trade guarantee obligations with respect to the Options E&A until certain deadlines [16] have

[7] According to the Clearing Agencies, regular way settlement is understood to be the financial services industry's standard settlement cycle. Currently, regular way settlement of securities underlying Stock Options and stock futures takes place on the third business day following the date the related exercise, assignment or delivery obligation is accepted by NSCC. On or prior to September 5, 2017, the standard settlement cycle will be shortened to two business days after trade date, as required by the Commission. *See* Securities Exchange Act Release No. 80295 (March 22, 2017), 82 FR 15564 (March 29, 2017) (S7–22–16) (Securities Transaction Settlement Cycle). NSCC has amended its Rules with respect to the meaning of regular way settlement to be consistent with the shorter standard settlement cycle and will establish an effective date for these rule changes in a subsequent rule filing. *See* Securities Exchange Act Release No. 79734 (January 4, 2017), 82 FR 3030 (January 10, 2017) (SR–NSCC–2016–007).

[8] A firm that is both an OCC Clearing Member and an NSCC Member, or is an OCC Clearing Member that has designated an NSCC Member to act on its behalf is referred to herein as a ''Common Member.''

[9] The New Accord would continue to provide for the settlement of securities underlying Stock Options that settle through NSCC's CNS Accounting Operation.

[10] Under the New Accord, ''regular way settlement'' would have a meaning agreed to by the Clearing Agencies. This will address any changes to the standard settlement cycle. *See supra* note 7.

[11] Such effective date would be a date following approval of all required regulatory submissions to be filed by OCC and NSCC with the appropriate regulatory authorities, including these Proposed Rule Changes. *See supra* note 3.

[12] *Supra* note 5.

[13] According to the Clearing Agencies, delivery of the OCC Transactions File with respect to an Options E&A typically happens on the date of the option's exercise or expiration, though this is not expressly stated in the Existing Accord. However, in theory, an Options E&A could, due to an error or delay, be reported later than the date of the option's exercise or expiration.

[14] According to the Clearing Agencies, this process would be substantially the same under the New Accord with the exception that the CNS Eligibility Master File and OCC Transactions File would be renamed and would be expanded in scope to include additional securities that would be eligible for guaranty and settlement under the New Accord, as discussed in further detail below.

[15] Pursuant to Addendum K of the NSCC Rules, NSCC guarantees the completion of CNS transactions and balance order transactions that have reached the point at which, for bi-lateral submissions by Members, such trades have been validated and compared by NSCC, and for locked-in submissions, such trades have been validated by NSCC, as described in the NSCC Rules. Transactions that are covered by the Existing Accord, and that would be covered by the New Accord, are expressly excluded from the timeframes described in Addendum K. *See supra* note 5.

[16] The deadline is 6:00 a.m. Central Time for NSCC notifying OCC of a Common Member failure

Continued

passed on the first business day following the scheduled settlement date. Once such deadlines have passed, OCC is released from its trade guarantee unless NSCC has notified OCC that the relevant Common Member has failed to meet an obligation to NSCC or NSCC has ceased to act for such Common Member pursuant to the NSCC Rules.[17] As a result, there is a period of time during which NSCC's trade guarantee overlaps with OCC's trade guarantee and for which both Clearing Agencies collect and hold margin from the Common Member.

In the event that NSCC or OCC ceases to act on behalf of or suspends a Common Member, that Common Member would become a ''defaulting member.'' Once a Common Member becomes a defaulting member, the Existing Accord provides that if OCC were to suspend a Common Member, NSCC would be required to make a payment to OCC equal to the lesser of OCC's total loss resulting from the closeout or the positive mark-to-market (''MTM'') amount relating to the defaulting member's Options E&A and that if NSCC were to suspend a Common Member, OCC would be required to make a payment to NSCC equal to the lesser of NSCC's total loss resulting from closeout or the negative mark-to-market amount relating to the defaulting member's Options E&A. A Clearing Agency must request the transfer of any such payments by the close of business on the tenth business day following the day of default and, after a request is made, the other Clearing Agency is required to make payment within five business days of the request.

The New Accord

Overview

As noted above, the Clearing Agencies propose to adopt a New Accord, which would provide for the settlement of certain securities underlying Stock Options and Stock Futures transactions. According to the Clearing Agencies, the New Accord is primarily designed to, among other things, expand the category of securities that are eligible for settlement and guaranty under the agreement; simplify the time of the transfer of responsibilities from OCC to NSCC (specifically, the Guaranty Substitution); and put additional arrangements into place concerning the procedures, information sharing, and overall governance processes under the agreement. The material provisions of the New Accord are described in detail below.

Key Elements of the New Accord

Expanded Scope of Eligible Securities

Pursuant to the proposed New Accord, on each day that both OCC and NSCC are open for accepting trades for clearing (''Activity Date''), NSCC would deliver to OCC an ''Eligibility Master File,'' which would identify the securities, including stocks, exchange-traded funds and exchange-traded notes, that are: (1) Eligible to settle through NSCC's CNS Accounting Operation (as is currently the case under the Existing Accord) or NSCC's Balance Order Accounting Operation (which is a feature of the New Accord) and (2) required to be physically delivered in settlement of (i) exercises and assignments of Stock Options (as is currently the case under the Existing Accord) or (ii) delivery obligations arising from maturing physically settled Stock Futures (which is a feature of the New Accord) (all such securities collectively being ''Eligible Securities''). OCC, in turn, would deliver to NSCC its file of E&A/Delivery Transactions [18] that list the Eligible Securities to be delivered, or received, and for which settlement is proposed to be made through NSCC on that Activity Date. Guaranty Substitution (discussed further below) would not occur with respect to an E&A/Delivery Transaction that is not submitted in the proper format or that involves a security that is not identified as an Eligible Security on the then-current Eligibility Master File. This process is similar to the current process under the Existing Accord with the exception of the expanded scope of Eligible Securities (and additional fields necessary to accommodate such securities) that would be listed on the Eligibility Master File and the E&A/Delivery Transactions file.

As with the Existing Accord, the proposed New Accord would continue to provide for the settlement of securities underlying Stock Options that settle through NSCC's CNS Accounting Operation and are designated to settle regular way. In addition, the New Accord would expand the category of securities eligible for settlement and guarantee by NSCC to include Stock Futures deliveries that are eligible to settle through NSCC's CNS Accounting Operation and are designated to settle regular way. The New Accord would also provide for the settlement of securities underlying both Stock Options and Stock Futures that are eligible to settle through NSCC's Balance Order Accounting Operation on a regular way basis. The primary purpose of expanding the category of securities that are eligible for settlement and guaranty under the agreement is to provide consistent treatment across all expiries for products with regular way settlement cycle specifications and simplify the settlement process for these additional securities transactions.

The New Accord would not apply to Stock Options or Stock Futures that are designated to settle on a shorter timeframe than the regular way settlement timeframe. These Stock Options would continue to be processed and settled as they would be today, outside of the New Accord. The New Accord also would not apply to any Stock Options or Stock Futures with underlying securities that are neither CNS Securities nor Balance Order Securities.[19] Transactions in these securities are, and would continue to be processed on a trade-for-trade basis away from NSCC's facilities. Such transactions may utilize other NSCC services for which they are eligible, but would not be subject to the New Accord.[20]

Proposed Changes Related to Guaranty Substitution

The New Accord would adopt a fundamentally different approach to the delineation of the rights and responsibilities of the Clearing Agencies with respect to Guaranty Substitution.

As described above, the Existing Accord provides that, following the default of a Common Member, and depending on the timing of the exercise or assignment guarantee, the Clearing Agency that suspends the Common Member will receive payment from the other Clearing Agency to compensate for potential losses incurred in connection

and, if NSCC does not immediately cease to act for such defaulting Common Member, 4:00 p.m. Central Time for notifying OCC that NSCC has ceased to act.

[17] *See* NSCC Rule 46 (Rule 46 (Restrictions on Access to Services). *See supra* note 5.

[18] ''E&A/Delivery Transactions'' are transactions involving the settlement of securities underlying Stock Options and Stock Futures under the New Accord. The delivery of E&A/Delivery Transactions to NSCC would replace the delivery of the ''OCC Transactions File'' from the Existing Accord. The actual information delivered by OCC to NSCC would be the same as is currently provided on the OCC Transactions File, but certain additional terms would be included to accommodate the inclusion of Stock Futures, along with information regarding the date that the instruction to NSCC was originally created and the E&A/Delivery Transaction's designated settlement date.

[19] Balance Order Securities are defined in NSCC Rule 1, and are generally securities, other than foreign securities, that are eligible to be cleared at NSCC but are not eligible for processing through the CNS Accounting Operation. *See supra* note 5.

[20] OCC will continue to guarantee settlement until settlement actually occurs with respect to these Stock Options and Stock Futures.

with the Common Member's default. The proposed New Accord, in contrast, would clearly delineate a point in time at which OCC's Guaranty ends and NSCC's Guaranty begins (*i.e.,* the Guaranty Substitution takes place) with respect to E&A/Delivery Transactions. By focusing on the timing of the Guaranty Substitution, rather than payment from one Clearing Agency to the other, the New Accord would simplify the agreement and the procedures for situations involving the default of a Common Member. The New Accord additionally would minimize ''double-margining'' situations when a Common Member may simultaneously owe margin to both NSCC and OCC with respect to the same E&A/Delivery Transaction.

Under the New Accord, after NSCC has received an E&A/Delivery Transaction, the Guaranty Substitution would normally occur when NSCC has received all Required Deposits to its Clearing Fund, calculated taking into account such E&A/Delivery Transaction, of Common Members (''Guaranty Substitution Time'').[21] At the Guaranty Substitution Time, NSCC's Guaranty would take effect, and OCC would no longer retain any settlement obligations with respect to such E&A/Delivery Transactions.

The Guaranty Substitution would not occur, however, with respect to any E&A/Delivery Transaction if NSCC has rejected such E&A/Delivery Transaction due to an improper submission, as described above. The Guaranty Substitution also would not occur if, after NSCC's receipt of the E&A/Delivery Transaction but prior to receiving corresponding Clearing Fund deposits, a Common Member involved in the E&A/Delivery Transaction has defaulted on its obligations to NSCC by failing to meet its Clearing Fund obligations, or NSCC has otherwise ceased to act for such Common Member pursuant to the NSCC Rules (in either case, such Common Member becomes a ''Defaulting NSCC Member'').

NSCC would be required to promptly notify OCC if a Common Member becomes a Defaulting NSCC Member, as described above. Upon receiving such a notice, OCC would not submit to NSCC any additional E&A/Delivery Transactions involving the Defaulting NSCC Member for settlement, unless authorized representatives of both OCC and NSCC otherwise consent. OCC would, however, deliver to NSCC a list of all E&A/Delivery Transactions that have already been submitted to NSCC and that involve the Defaulting NSCC Member (''Defaulted NSCC Member Transactions''). The Guaranty Substitution would not occur with respect to such Defaulted NSCC Member Transactions, unless both Clearing Agencies agree otherwise. Therefore, NSCC would have no obligation to guarantee such Defaulted NSCC Member Transactions, and OCC would continue to be responsible for effecting the settlement of such Defaulted NSCC Member Transactions pursuant to OCC's By-Laws and Rules. Once NSCC has confirmed the list of Defaulted NSCC Member Transactions, Guaranty Substitution would occur for all submitted E&A/Delivery Transactions for that Activity Date that are not included on such list (*i.e.,* those transactions not involving the Defaulting NSCC Clearing Member). NSCC would be required to promptly notify OCC upon the occurrence of the Guaranty Substitution Time on each Activity Date.

If OCC suspends a Common Member after NSCC has received the E&A/Delivery Transactions but before the Guaranty Substitution has occurred, and that Common Member has not become a Defaulting NSCC Member, the Guaranty Substitution would proceed at the Guaranty Substitution Time. In such a scenario, OCC would continue to be responsible for guaranteeing the settlement of the E&A/Delivery Transactions in question until the Guaranty Substitution Time, at which time the responsibility would transfer to NSCC. If, however, the suspended Common Member also becomes a Defaulting NSCC Member after NSCC has received the E&A/Delivery Transactions but before the Guaranty Substitution has occurred, Guaranty Substitution would not occur, and OCC would continue to be responsible for effecting the settlement of such Defaulted NSCC Member Transactions pursuant to OCC's By-Laws and Rules (unless both Clearing Agencies agree otherwise).

Finally, the New Accord also would provide for the consistent treatment of all exercise and assignment activity under the agreement. Under the Existing Accord, ''standard'' [22] option contracts become guaranteed by NSCC when the Common Member meets its morning Clearing Fund Required Deposit at NSCC while ''non-standard'' exercise and assignment activity becomes guaranteed by NSCC at midnight of the day after trade date (T+1). Under the New Accord, all exercise and assignment activity for Eligible Securities would be guaranteed by NSCC as of the Guaranty Substitution Time, under the circumstances described above, further simplifying the framework for the settlement of such contracts.

Other Terms of the New Accord

The New Accord would include a number of other provisions intended to maintain certain terms of the Existing Accord or improve the procedures, information sharing, and overall governance process under the new agreement. Many of these terms are additions to or improvements upon the terms of the Existing Accord.

Under the proposed New Accord, the Clearing Agencies would agree to address the specifics regarding the time, form, and manner of various required notifications and actions in a separate service level agreement, which the parties would be able to revisit as their operational needs evolve. The separate service level agreement also would specify an effective date for the New Accord, which would occur on a date following approval and effectiveness of all required regulatory submissions to be filed by OCC and NSCC with the appropriate regulatory authorities. Similar to the Existing Accord, the proposed New Accord would remain in effect: (a) Until it is terminated by the mutual written agreement of OCC and NSCC; (b) until it is unilaterally terminated by either Clearing Agency upon one year's written notice (as opposed to six months under the Existing Accord); or (c) until it is terminated by either NSCC or OCC upon the bankruptcy or insolvency of the other, provided that the election to terminate is communicated to the other party within three business days by written notice.

Under the proposed New Accord, NSCC would agree to notify OCC if NSCC ceases to act for a Common Member pursuant to the NSCC Rules no later than the earlier of NSCC's provision of notice of such action to the governmental authorities or notice to other NSCC Members. Furthermore, if an NSCC Member for which NSCC has not yet ceased to act fails to satisfy its Clearing Fund obligations to NSCC, NSCC would be required to notify OCC promptly after discovery of the failure. Likewise, OCC would be required to notify NSCC of the suspension of a Common Member no later than the earlier of OCC's provision of notice to

[21] Procedure XV of the NSCC Rules provides that all Clearing Fund requirements and other deposits be made within one hour of demand, unless NSCC determines otherwise. *See supra* note 5.

[22] Option contracts with ''standard'' expirations expire on the third Friday of the specified expiration month, while ''non-standard'' contracts expire on other days of the expiration month.

the governmental authorities or other OCC Clearing Members.

Under the Existing Accord, NSCC and OCC agree to share certain reports and information regarding settlement activity and obligations under the agreement. The New Accord would enhance this information sharing between the Clearing Agencies. For example, the Clearing Agencies would agree to share certain information, including general risk management due diligence regarding Common Members, lists of Common Members, and information regarding margin and settlement obligations of the Common Members. The Clearing Agencies would also agree to provide each other with any other information that the other reasonably requests in connection with their obligations under the New Accord. All such information would be required to be kept confidential, using the same care and discretion that each Clearing Agency uses for the safekeeping of its own members' confidential information. NSCC and OCC would each be required to act in good faith to resolve and notify the other of any errors, discrepancies or delays in the information it provides.

The New Accord also would include new terms to provide that, to the extent a Clearing Agency is unable to perform any obligation as a result of the failure of the other Clearing Agency to perform its responsibilities on a timely basis, the time for the non-failing Clearing Agency's performance would be extended, its performance would be reduced to the extent of any such impairment, and it would not be liable for any failure to perform its obligations. Further, NSCC and OCC would agree that neither Clearing Agency would be liable to the other Clearing Agency in connection with its performance of its obligations under the proposed New Accord to the extent it has acted, or omitted or ceased to act, with the permission or at the direction of a governmental authority. Moreover, the proposed New Accord would provide that in no case would either Clearing Agency be liable to the other for punitive, incidental or consequential damages. The purpose of these new provisions is to provide clear and specific terms regarding each Clearing Agency's liability for non-performance under the agreement.

The proposed New Accord would also contain the usual and customary representations and warranties for an agreement of this type, including representations as to the parties' good standing, corporate power and authority and operational capability, that the agreement complies with laws and all government documents and does not violate any agreements, and that all of the required regulatory notifications and filings would be obtained prior to the New Accord's effective date. It would also include representations that the proposed New Accord constitutes a legal, valid and binding obligation on each of OCC and NSCC and is enforceable against each, subject to standard exceptions. Furthermore, the proposed New Accord would contain a force majeure provision, under which NSCC and OCC would agree to notify the other no later than two hours upon learning that a force majeure event has occurred and both parties would be required to cooperate in good faith to mitigate the effects of any resulting inability to perform or delay in performing.

Proposed Amendments to NSCC Rules

Given the key differences between the Existing Accord and the New Accord, as described above, NSCC proposes certain changes to Procedures III and XV of the NSCC Rules to accommodate the terms of the New Accord. In particular, NSCC would update Section B of Procedure III to define the scope of the New Accord. First, the proposed Section B of Procedure III would identify the E&A/Delivery Transactions, and would make clear that the New Accord would apply only to E&A/Delivery Transactions that are in either CNS Securities or Balance Order Securities, as such terms are defined in the NSCC Rules. The proposed Section B of Procedure III would also define the Common Members, or firms that must be named as counterparties to E&A/Delivery Transactions, as ''Participating Members.'' The proposal would describe the Guaranty Substitution Time and would describe the circumstances under which the Guaranty Substitution would not occur. Finally, the proposed Section B of Procedure III would describe how E&A/Delivery Transactions for which the Guaranty Substitution has occurred would be processed at NSCC both if they are covered by the proposed New Accord and if they are not covered by the proposed New Accord because, for example, they are not transactions in CNS Securities or Balance Order Securities or were not submitted for regular way settlement.

Finally, NSCC is also proposing to amend Procedure XV to remove reference to the exclusion of E&A/Delivery Transactions from the calculation of the mark-to-market margin component of its Clearing Fund calculations, which is no longer applicable under the proposed New Accord where the Guaranty Substitution would replace the transfer of a defaulting Common Member's margin payments under the Existing Accord. Therefore, NSCC is not proposing any change to its margining methodology, but will include E&A/Delivery Transactions in the calculation of the mark-to-market margin component of Common Members' Clearing Fund Required Deposits following implementation of the New Accord.

Proposed Amendments to OCC's By-Laws and Rules

OCC also proposes certain changes to its By-Laws and Rules to accommodate the terms of the New Accord. The primary purpose of the proposed changes is to: (1) Reflect the expanded scope of the New Accord, (2) reflect changes related to the new Guaranty Substitution mechanics of the New Accord; and (3) make other changes necessary to conform to the terms of the New Accord or to otherwise provide additional clarity around the settlement and margining [23] treatment of: (i) Eligible Securities under the New Accord, (ii) non-regular way securities settling through the facilities of NSCC but outside of the New Accord, and (iii) those securities settling outside of the New Accord and away from NSCC on a broker-to-broker basis. These proposed changes are discussed in greater detail below.

Changes Related to the Expanded Scope of the New Accord

First, OCC proposes to amend and replace the defined term ''CNS-eligible'' [24] to reflect the expanded definition of Eligible Securities under the New Accord. The term ''CNS-eligible'' currently describes the securities underlying the physically-settled stock options that are eligible under the Existing Accord to be settled through NSCC's CNS Accounting Operation. Under the New Accord, however, the term Eligible Securities is more broadly defined to include securities (both Stock Options and Stock Futures) eligible for settlement via NSCC's CNS Accounting Operation and NSCC's Balance Order Accounting Operation. Accordingly, OCC proposes to use ''CCC,'' for ''correspondent

[23] OCC notes that, while it is proposing changes to its Rules concerning margin requirements (*e.g.,* which transactions would be included as part of OCC's margin calculation at a given point in time), OCC is not proposing any changes to its margin model (with the exception that OCC would no longer collect and hold margin for positions after NSCC's Guaranty has taken effect under the New Accord).

[24] *See* Article I, Section (C)(23) of OCC's By-Laws.

clearing corporation'' [25] to describe the Eligible Securities. Thus, the term ''CCC-eligible'' would replace ''CNS-eligible'' throughout OCC's By-Laws and Rules.

Next, because the New Accord would include the settlement of securities underlying Stock Futures, OCC proposes to make several changes to its rules regarding Stock Futures to accommodate this expansion. More specifically, OCC proposes a conforming amendment to Rule 901 Interpretation and Policy (.02) to clarify that, under the New Accord, OCC will, subject to its discretion, cause the settlement of all matured Stock Futures to be made through the facilities of NSCC to the extent that the underlying securities are CCC-eligible as the term is currently proposed.

OCC also proposes clarifying and conforming revisions to newly renumbered Rule 901(e) (currently Rule 901(d)) to specify that settlements made through the facilities of the correspondent clearing corporation are governed by Rule 901 and to clarify that, under the New Accord, specifications made in any Delivery Advice may be revoked up until the point at which NSCC's Guaranty has taken effect (the ''obligation time'' as discussed below) and not the opening of business on the delivery date.

Changes Related to Guaranty Substitution

OCC also proposes a series of amendments to its Rules to accurately reflect the process under which the Guaranty Substitution occurs under the New Accord. First, OCC proposes to amend Rule 901(c) so that the term ''obligation time''—the time that the correspondent clearing corporation becomes unconditionally obligated, in accordance with its rules, to effect settlement in respect thereof or to close out the securities contract arising therefrom—is synonymous with the Guaranty Substitution Time under the New Accord (*i.e.,* (i) settlement obligations are reported to and are not rejected by NSCC; (ii) NSCC has not notified OCC that NSCC has ceased to act for the relevant Clearing Member; and (iii) the Clearing Fund requirements of the relevant Clearing Member are received by NSCC). Under the New Accord, if a default occurs prior to the Guaranty Substitution Time, the Guaranty Substitution will not occur for any E&A/Delivery Transactions involving the Defaulting NSCC Member, and OCC will continue to guarantee settlement for those Defaulted NSCC Member Transactions.

Next, OCC proposes to amend language in newly renumbered Rule 901(i) (currently Rule 901(h)) regarding the timing of the end of a Clearing Member's obligations to OCC with respect to securities to be settled through NSCC. Under the Existing Accord and OCC's existing Rules, a Clearing Member's obligations to OCC end only once settlement is completed. Under the New Accord, however, a Clearing Member's obligations to OCC will end when OCC's obligations with respect to guaranteeing settlement of the security would end (*i.e.,* the Guaranty Substitution Time or ''obligation time''). OCC therefore proposes to amend newly renumbered Rule 901(i) to specify that a Clearing Member's obligations to OCC will be deemed completed and performed once the ''obligation time'' has occurred.

As discussed above, the New Accord eliminates the provisions of the Existing Accord whereby OCC and NSCC guaranteed each other the performance of Common Members and made certain payments to the other upon the default of a Common Member. Therefore, OCC proposes to delete discussions of such guarantees and payments from newly renumbered Rule 901(i) and Rule 1107.

OCC also proposes amendments to Rules 910 and 911, which set forth procedures for handling failures to make or take delivery of securities in settlement of exercised or assigned Stock Options and matured physically-settled Stock Futures, to add language to both rules to clarify that the failure procedures set forth therein would not apply with respect to any delivery to be made through NSCC pursuant to Rule 901. Under the New Accord, once the Guaranty Substitution Time with respect to a specific E&A/Delivery Transaction occurs, OCC's Guaranty ends and NSCC's Guaranty begins, leaving OCC with no involvement with or responsibility for the settlement of the securities underlying that transaction. Therefore, if there is a failure to make or take delivery with respect to that transaction after Guaranty Substitution has occurred, the NSCC Rules will govern that failure. With respect to deliveries made on a broker-to-broker basis under OCC Rules 903 through 912 (including those that may utilize NSCC's Obligation Warehouse services), and which are not governed by Rule 901, Guaranty Substitution does not occur and OCC's failure procedures would apply.

Changes to OCC's Margin Rules

Under the New Accord, OCC will no longer collect margin on a transaction once it is no longer guaranteeing settlement for that transaction. Therefore, OCC proposes to add language to Rule 601(f) to clarify that OCC's margin calculations will not include delivery obligations arising from any Stock Options or Stock Futures that are eligible for settlement through NSCC and for which OCC has no further settlement obligations because either (i) Guaranty Substitution has occurred for E&A/Delivery Transactions under the New Accord (as described in revised Rule 901(c)) or (ii) NSCC has otherwise accepted transactions for non-regular way settlement under the NSCC Rules (as describe in newly proposed Rule 901(d)).[26] By not including these transactions as part of OCC's margin calculation, OCC is hoping to alleviate instances of ''double-margining'' for Common Members that may otherwise simultaneously owe margin to NSCC and OCC with respect to the same position.

OCC also proposes to delete Rule 608A in its entirety. The New Accord seeks to eliminate the situation under the Existing Accord where Common Members are effectively ''double-margined'' or required to simultaneously post margin with OCC and NSCC with respect to the same position. As the New Accord eliminates this double-margining scenario, Rule 608A, which provides procedures pursuant to which a Clearing Member could use the securities deposited as margin with OCC as collateral to secure a loan to pay its margin obligations to NSCC, is now unnecessary.

Other Clarifying Changes Not Related to the New Accord

OCC also proposes to amend its Rules to make clarifying changes that are not directly required by the New Accord but would provide additional clarity in its Rules in light of other changes being made to accommodate the New Accord. Specifically, OCC proposes to revise Rule 901 Interpretation and Policy (.02) to provide that transactions that involve the delivery of non-CCC eligible securities made on a broker-to-broker basis (and away from NSCC) may

[25] Under Article I of OCC's By-Laws, the term ''correspondent clearing corporation'' means the National Securities Clearing Corporation or any successor thereto which, by agreement with the Corporation, provides facilities for settlements in respect of exercised option contracts or BOUNDs (*i.e.,* securities issued by OCC pursuant to Article XXIV of OCC's By-Laws and Chapter XXV of OCC's Rules) or in respect of delivery obligations arising from physically-settled stock futures. *See supra* note 5.

[26] Related revisions to Rule 901(c) and newly proposed Rule 901(d) are discussed in more detail below.

nevertheless involve the use of certain services of NSCC (*e.g.,* NSCC's Obligation Warehouse). For such transactions, because they are not covered by the New Accord and NSCC at no point guarantees settlement, OCC Rule 901 would not apply and delivery is governed by the broker-to-broker settlement procedures set forth in OCC Rules 903 through 912, as is the case currently today. Additionally, while OCC's existing Rules do not prohibit broker-to-broker settlements from being facilitated through the services of a correspondent clearing corporation, they do not explicitly contemplate the possibility. OCC also proposes to make clarifying amendments to Rule 904(b) and 910A(a) to more clearly distinguish between settlements effected through NSCC's CNS Accounting Operation or Balance Order Accounting Operations in accordance with OCC Rule 901 and deliveries effected on a broker-to-broker basis utilizing services of NSCC under OCC Rules 903 through 912 and to clearly state which OCC Rules apply in each context.

Further, OCC proposes to add a new paragraph (d) to Rule 901 to clarify that OCC still intends, at its discretion, to effect settlement of Stock Options and Stock Futures that are scheduled to be settled on the first business day after exercise or maturity through NSCC pursuant to Rule 901 and the relevant provisions of the NSCC Rules, even though such contracts are outside the scope of the New Accord. These contracts would continue to be settled as they are currently today.

OCC also proposes clarifying and conforming changes to the introductory language of Chapter IX of the Rules. Specifically, OCC proposes conforming changes to the Rule to reflect the replacement of the defined term ''CNS-eligible'' with ''CCC-eligible'' as described above. The proposed changes would also clarify that OCC's broker-to-broker settlement rules are contained in Rules 903–912, as Rule 902 concerns Delivery Advices, which also may be applicable to settlements made through the correspondent clearing corporation pursuant to Rule 901. In addition, the proposed changes to the introductory language of Chapter IX of the Rules would provide additional clarity around OCC's existing authority to alter a previous designation of a settlement method at any time prior to the designated delivery date by specifying that this authority would apply to both settlements to be made through the facilities of the correspondent clearing corporation pursuant to Rule 901 or settlements to be made on a broker-to-broker basis pursuant to Rules 903 through 912. Finally, OCC proposes a number of conforming changes to Rules 901 and 912 to reflect the renumbering of various Rule provisions due to the proposed amendments described above.

II. Discussion and Commission Findings

Section 19(b)(2)(C) of the Act directs the Commission to approve a proposed rule change of a self-regulatory organization if it finds that such proposed rule change is consistent with the requirements of the Act and rules and regulations thereunder applicable to such organization.[27] After carefully considering the Proposed Rule Changes, the Commission finds that the Proposed Rule Changes are consistent with the requirements of the Act and the rules and regulations thereunder applicable to the Clearing Agencies. In particular, the Commission believes the proposal is consistent with Section 17A(b)(3)(F) of the Act,[28] as well as Rules 17Ad–22(e)(20) and (21).[29]

A. Consistency With Section 17A(b)(3)(F) of the Act

Section 17A(b)(3)(F) of the Act requires, in part, that the rules of a clearing agency be designed to promote the prompt and accurate clearance and settlement of securities transactions, to assure the safeguarding of securities and funds which are in the custody or control of the clearing agency or for which it is responsible, and to foster cooperation and coordination with persons engaged in the clearance and settlement of securities transactions.[30] The Commission believes that the Proposed Rule Changes are consistent with the requirements of Section 17A(b)(3)(F) of the Act for the reasons set forth below.

The proposal would expand the category of securities eligible for settlement and guarantee under the New Accord to include Stock Futures deliveries that are eligible to settle through NSCC's CNS Accounting Operation, as well as securities underlying Stock Options and Stock Futures that are eligible to settle through NSCC's Balance Order Accounting Operation, where each are scheduled to settle regular way. By including these additional securities as part of the New Accord, the proposal would provide for more uniform settlement processing of securities with regular way settlement. According to the Clearing Agencies, the expansion of the category of securities eligible for settlement and guarantee under the New Accord would simplify the settlement process for these additional securities transactions. By providing for more uniform settlement processing, simplifying the settlement process, and subjecting such transactions to enhanced information sharing and governance, as described below, this change would promote the prompt and accurate clearance and settlement of these additional securities transactions.

The proposal would establish additional arrangements concerning the procedures, information sharing, and overall governance processes under the New Accord. For example, the Clearing Agencies would agree to share certain information, including general risk management due diligence regarding Common Members, lists of Common Members, and information regarding margin and settlement obligations of the Common Members. The Clearing Agencies also would agree to provide each other with any other information that the other reasonably requests in connection with their obligations under the New Accord. Such arrangements would foster cooperation and coordination between OCC and NSCC in the settlement of securities transactions.

The New Accord also would establish the Guaranty Substitution Time (*i.e.,* a specific point in time where trade guarantee obligations would transfer from OCC to NSCC), with respect to the applicable securities transactions, as described above. The Guaranty Substitution Time would help eliminate ambiguity and complexity that exists in the current guarantee practice regarding which Clearing Agency is responsible for guaranteeing settlement at any given moment, and help provide greater certainty that, in the event of the default of a Common Member, the default would be handled pursuant to the rules and procedures of the Clearing Agency whose guarantee is then in effect. This proposed change is designed to help strengthen the Clearing Agencies' abilities to plan for, manage, and, therefore, mitigate the risks that the default of a Common Member could present to the Clearing Agencies, other clearing members, and the market as a whole, thereby promoting the prompt and accurate clearance and settlement of securities transactions.

The proposed changes to the NSCC Rules would provide additional clarity, transparency, and certainty around the application of the New Accord to the applicable E&A/Delivery Transactions. Other proposed changes to OCC's Rules also would provide additional clarity, transparency, and certainty around the

[27] 15 U.S.C. 78s(b)(2)(C).

[28] 15 U.S.C. 78q–1(b)(3)(F).

[29] 17 CFR 240.17Ad–22(e)(20) and (21).

[30] 15 U.S.C. 78q–1(b)(3)(F).

settlement and margining treatment of various securities transactions cleared by OCC (including those settled under the New Accord, those otherwise settled through the facilities of NSCC, and those that settle on a broker-to-broker basis away from NSCC). By providing Clearing Members with this additional clarity, transparency, and certainty in the NSCC Rules and OCC's Rules, the Proposed Rule Changes are designed to promote the prompt and accurate clearance and settlement of securities transactions and assure the safeguarding of securities and funds which are in the custody or control of the Clearing Agencies or for which they are responsible.

Therefore, for the reasons stated above, the Commission believes that the Proposed Rule Changes are consistent with the requirements of Section 17A(b)(3)(F) of the Act.[31]

B. Consistency With Rule 17Ad–22(e)(20)

The Commission believes that the changes proposed in the Proposed Rule Changes are consistent with Rule 17Ad–22(e)(20) under the Act, which requires, in part, that the Clearing Agencies establish, implement, maintain and enforce written policies and procedures reasonably designed to identify, monitor, and manage risks related to any link the clearing agency establishes with one or more other clearing agencies.[32]

Under the terms of the Existing Accord, even after NSCC's trade guarantee has taken effect, OCC is not released from its trade guarantee with respect to the transactions until certain deadlines have passed, as discussed above. As a result, the Existing Accord creates a complicated framework for the settlement of securities underlying certain Stock Options, which could lead to an unanticipated disruption to the Clearing Agencies' respective clearing operations.

The New Accord is designed to better mitigate and manage the risks related to the link the Clearing Agencies have established with each other to settle the securities underlying Stock Options and Stock Futures. For example, by instituting the Guaranty Substitution Time, the New Accord would provide for a clearer, simpler framework for the settlement of securities underlying certain Stock Options and Stock Futures by setting a specific time at which trade guarantee obligations would transfer from OCC to NSCC. This would help eliminate the ambiguity that currently exists regarding which Clearing Agency is responsible for guaranteeing settlement at any given moment. It would also provide greater certainty that in the event of a Common Member default, the default would be handled pursuant to the rules and procedures of the Clearing Agency whose guarantee is then in effect. This greater certainty, in turn, is designed to help improve the OCC's and NSCC's ability to plan for and manage the risk presented by the default of a Common Member, and the effects that such a default could have on other members and the markets the Clearing Agencies serve.

In connection with the proposal to put additional arrangements into place concerning the procedures, information sharing, and overall governance processes under the New Accord, the Clearing Agencies would agree to share certain information, including general surveillance information regarding their members. Such arrangements are designed to help each Clearing Agency more effectively identify, monitor, and manage risks that may be presented by Common Members.

For the above reasons, the Commission believes that the New Accord is designed to assist the Clearing Agencies in identifying, monitoring, and managing risks related to the link between the Clearing Agencies. Therefore, the Commission believes that the changes proposed in the Proposed Rule Changes are consistent with Rule 17Ad–22(e)(20).[33]

C. Consistency With Rule 17Ad–22(e)(21)

The Commission believes that the proposal is consistent with Rule 17Ad–22(e)(21) under the Act, which requires, in part, that the Clearing Agencies establish, implement, maintain and enforce written policies and procedures reasonably designed to be efficient and effective in meeting the requirements of its participants and the markets it serves.[34] As described above, the proposal would modify the timing of the Guaranty Substitution by establishing the Guaranty Substitution Time. In doing so, the New Accord would minimize the ''double margining'' issue [35] that is present under the Existing Accord. As a result, Common Members would no longer be required to post margin at both Clearing Agencies to cover the same transactions. By simplifying the terms of the existing agreement in this way, the New Accord is designed to be more efficient and effective in meeting the requirements of OCC's and NSCC's participants and the markets they serve.

Furthermore, as described above, the proposed changes would establish additional arrangements between the Clearing Agencies concerning the procedures, information sharing, and overall governance processes under the New Accord. Such arrangements could enhance information sharing between the Clearing Agencies and enable them to more effectively identify, monitor, and manage risks that may be presented by certain Common Members.

Because the New Accord would allow for greater information sharing and eliminate the need for Common Members to post margin at both Clearing Agencies for the same transactions, the Commission believes the proposal is designed to be efficient and effective in meeting the requirements of Common Members. Therefore, the Commission believes that the changes proposed in the Proposed Rule Changes are consistent with the requirements of Rule 17Ad–22(e)(21).[36]

III. Conclusion

On the basis of the foregoing, the Commission finds that the Proposed Rule Changes are consistent with the requirements of the Act, in particular the requirements of Section 17A of the Act [37] and the rules and regulations promulgated thereunder.

It is therefore ordered, pursuant to Section 19(b)(2) of the Act, that proposed rule changes SR–NSCC–2017–007 and SR–OCC–2017–013 be and hereby are Approved as of the date of this order or the date of a notice by the Commission authorizing the Clearing Agencies to implement their advance notice proposals (SR–NSCC–2017–803, SR–OCC–2017–804), whichever is later.[38]

[31] *Id.*

[32] 17 CFR 240.17Ad–22(e)(20).

[33] *Id.*

[34] 17 CFR 240.17Ad–22(e)(21).

[35] As noted above, under the Existing Accord, even after NSCC's trade guarantee has taken effect, OCC retains its trade guarantee obligations with respect to the options exercise or assignment until certain deadlines have passed on the first business day following the scheduled settlement date. Once such deadlines have passed, OCC is released from its trade guarantee unless NSCC has notified OCC that the relevant Common Member has failed to meet an obligation to NSCC or NSCC has ceased to act for such firm. This results in a period of time during which NSCC's trade guarantee overlaps with OCC's trade guarantee, for which both Clearing Agencies collect and hold margin from the Common Member. *See supra* note 16.

[36] 17 CFR 240.17Ad–22(e)(21).

[37] 15 U.S.C. 78q–1.

[38] In approving the Proposed Rule Changes, the Commission considered the proposals' impact on efficiency, competition, and capital formation. 15 U.S.C. 78c(f).

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[39]

Eduardo A. Aleman,

Assistant Secretary.

[FR Doc. 2017–16401 Filed 8–3–17; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

[Investment Company Act Release No. 32768; 812–14759]

Sharespost 100 Fund and SP Investments Management, LLC

July 31, 2017.

AGENCY: Securities and Exchange Commission (''Commission'').

ACTION: Notice.

Notice of an application under section 6(c) of the Investment Company Act of 1940 (the ''Act'') for an exemption from sections 18(a)(2), 18(c) and 18(i) of the Act, under sections 6(c) and 23(c)(3) of the Act for an exemption from rule 23c–3 under the Act, and for an order pursuant to section 17(d) of the Act and rule 17d–1 under the Act.

Summary of Application: Applicants request an order to permit certain registered closed-end management investment companies to issue multiple classes of shares and to impose asset-based distribution and/or service fees, early withdrawal charges (''EWCs'') and repurchase fees (''Repurchase Fees'').

Applicants: Sharespost 100 Fund (the ''Initial Fund'') and SP Investments Management, LLC (the ''Adviser'').

Filing Dates: The application was filed on April 6, 2017 and amended on May 17, 2017 and July 19, 2017.

Hearing or Notification of Hearing: An order granting the requested relief will be issued unless the Commission orders a hearing. Interested persons may request a hearing by writing to the Commission's Secretary and serving applicants with a copy of the request, personally or by mail. Hearing requests should be received by the Commission by 5:30 p.m. on August 25, 2017, and should be accompanied by proof of service on the applicants, in the form of an affidavit, or, for lawyers, a certificate of service. Pursuant to rule 0–5 under the Act, hearing requests should state the nature of the writer's interest, any facts bearing upon the desirability of a hearing on the matter, the reason for the request, and the issues contested. Persons who wish to be notified of a hearing may request notification by writing to the Commission's Secretary.

ADDRESSES: Secretary, U.S. Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090; Applicants: 101 Jefferson Drive, Menlo Park, California 94025.

FOR FURTHER INFORMATION CONTACT: Barbara T. Heussler, Senior Attorney, at (202) 551–6990, or Robert H. Shapiro, Branch Chief, at (202) 551–6821 (Division of Investment Management, Chief Counsel's Office).

SUPPLEMENTARY INFORMATION: The following is a summary of the application. The complete application may be obtained via the Commission's Web site by searching for the file number, or for an applicant using the Company name box, at *http://www.sec.gov/search/search.htm* or by calling (202) 551–8090.

Applicants' Representations

1. The Initial Fund is a Delaware statutory trust that is registered under the Act as a non-diversified, closed-end management investment company. The Initial Fund's investment objective is capital appreciation. The Initial Fund seeks to achieve its investment objective by investing in the equity securities of certain private, operating, late-stage growth companies primarily comprising the SharesPost 100, a list of companies selected and maintained by the Adviser.

2. The Adviser, a Delaware limited liability company, is registered as an investment adviser under the Investment Advisers Act of 1940. The Adviser serves as investment adviser to the Initial Fund.

3. The applicants seek an order to permit the Initial Fund to issue multiple classes of shares, each having its own fee and expense structure, and to impose asset-based distribution and/or service fees, EWCs and Repurchase Fees.

4. Applicants request that the order also apply to any continuously offered registered closed-end management investment company that has been previously organized or that may be organized in the future for which the Adviser, or any entity controlling, controlled by, or under common control with the Adviser, or any successor in interest to any such entity,[1] acts as investment adviser and which operates as an interval fund pursuant to rule 23c–3 under the Act or provides periodic liquidity with respect to its shares pursuant to rule 13e–4 under the Securities Exchange Act of 1934 (''Exchange Act'') (each, a ''Future Fund'' and together with the Initial Fund, the ''Funds'').[2]

5. The Initial Fund is currently making a continuous public offering of its common shares. Applicants state that additional offerings by any Fund relying on the order may be on a private placement or public offering basis. Shares of the Funds will not be listed on any securities exchange nor quoted on any quotation medium. The Funds do not expect there to be a secondary trading market for their shares.

6. If the requested relief is granted, the Initial Fund intends to redesignate its common shares as ''Class A Shares'' and to amend its registration statement in order to continuously offer an additional class of shares, designated as ''Class I Shares''. Each of the Class A Shares and Class I Shares will have its own fee and expense structure. The Funds may in the future offer additional classes of shares and/or another sales charges structure. Because of the different distribution and/or service fees, services and any other class expenses that may be attributable to the Class A Shares and Class I Shares, the net income attributable to, and the dividends payable on, each class of shares may differ from each other.

7. Applicants state that, from time to time, the Initial Fund may create additional classes of shares, the terms of which may differ from Class A Shares and Class I Shares in the following respects: (i) The amount of fees permitted by different distribution plans and/or different service fee arrangements; (ii) voting rights with respect to a distribution and/or service plan of a class; (iii) different class designations; (iv) the impact of any class expenses directly attributable to a particular class of shares allocated on a class basis as described in the application; (v) any differences in dividends and net asset value resulting from differences in fees under a distribution and/or service plan or in class expenses; (vi) any EWC or other sales load structure; and (vii) exchange or conversion privileges of the classes as permitted under the Act.

8. Applicants state that shares of a Fund will be subject to a Repurchase Fee at a rate of no greater than 2% of the aggregate net asset value of a shareholder's shares repurchased by the Fund if the interval between the date of purchase of the shares and the valuation date with respect to the repurchase of those shares is less than one year.

[39] 17 CFR 200.30–3(a)(12).

[1] A successor in interest is limited to an entity that results from a reorganization into another jurisdiction or a change in the type of business organization.

[2] Any Fund relying on this relief in the future will do so in a manner consistent with the terms and conditions of the application. Applicants represent that each entity presently intending to rely on the requested relief is listed as an applicant.

Repurchase Fees will apply equally to new class shares and to all classes of shares of a Fund, consistent with section 18 of the Act and rule 18f–3 thereunder. To the extent a Fund determines to waive, impose scheduled variations of, or eliminate a Repurchase Fee, it will do so consistently with the requirements of rule 22d–1 under the Act as if the Repurchase Fee were a CDSL (defined below) and as if the Fund were an open-end investment company and the Fund's waiver of, scheduled variation in, or elimination of, the Repurchase Fee will apply uniformly to all shareholders of the Fund regardless of class.

9. Applicants state that the Initial Fund has adopted a fundamental policy to repurchase a specified percentage of its shares (no less than 5% and no more than 25%) at net asset value on a quarterly basis. Such repurchase offers will be conducted pursuant to rule 23c–3 under the Act. Each of the other Funds will likewise adopt fundamental investment policies and make periodic repurchase offers to its shareholders in compliance with rule 23c–3 or will provide periodic liquidity with respect to its shares pursuant to rule 13e–4 under the Exchange Act.[3] Any repurchase offers made by the Funds will be made to all holders of shares of each such Fund.

10. Applicants represent that any asset-based service and distribution fees for each class of shares of the Funds will comply with the provisions of the Financial Industry Regulatory Authority (''FINRA'') Rule 2341 (''FINRA Sales Charge Rule'').[4] Applicants also represent that each Fund will disclose in its prospectus the fees, expenses and other characteristics of each class of shares offered for sale by the prospectus, as is required for open-end multiple class funds under Form N–1A. As is required for open-end funds, each Fund will disclose its expenses in shareholder reports, and describe any arrangements that result in breakpoints in or elimination of sales loads in its prospectus.[5] In addition, applicants will comply with applicable enhanced fee disclosure requirements for fund of funds, including registered funds of hedge funds.[6]

11. Each of the Funds will comply with any requirements that the Commission or FINRA may adopt regarding disclosure at the point of sale and in transaction confirmations about the costs and conflicts of interest arising out of the distribution of open-end investment company shares, and regarding prospectus disclosure of sales loads and revenue sharing arrangements, as if those requirements applied to the Fund. In addition, each Fund will contractually require that any distributor of the Fund's shares comply with such requirements in connection with the distribution of such Fund's shares.

12. Each Fund will allocate all expenses incurred by it among the various classes of shares based on the net assets of that Fund attributable to each class, except that the net asset value and expenses of each class will reflect the expenses associated with the distribution and/or service plan of that class, service fees, and any other incremental expenses of that class. Expenses of a Fund allocated to a particular class of shares will be borne on a pro rata basis by each outstanding share of that class. Applicants state that each Fund will comply with the provisions of rule 18f–3 under the Act as if it were an open-end investment company.

13. Applicants state that each Fund may impose an EWC on shares submitted for repurchase that have been held less than a specified period and may waive the EWC for certain categories of shareholders or transactions to be established from time to time. Applicants state that each Fund will apply the EWC (and any waivers or scheduled variations of the EWC) uniformly to all shareholders in a given class and consistently with the requirements of rule 22d–1 under the Act as if the Funds were open-end investment companies.

14. Each Fund operating as an interval fund pursuant to rule 23c–3 under the Act may offer its shareholders an exchange feature under which the shareholders of the Fund may, in connection with such Fund's periodic repurchase offers, exchange their shares of the Fund for shares of the same class of (i) registered open-end investment companies or (ii) other registered closed-end investment companies that comply with rule 23c–3 under the Act and continuously offer their shares at net asset value, that are in the Fund's group of investment companies (collectively, ''Other Funds''). Shares of a Fund operating pursuant to rule 23c–3 that are exchanged for shares of Other Funds will be included as part of the amount of the repurchase offer amount for such Fund as specified in rule 23c–3 under the Act. Any exchange option will comply with rule 11a–3 under the Act, as if the Fund were an open-end investment company subject to rule 11a–3. In complying with rule 11a–3, each Fund will treat an EWC as if it were a contingent deferred sales load (''CDSL'').

Applicants' Legal Analysis

Multiple Classes of Shares

1. Section 18(a)(2) of the Act provides that a closed-end investment company may not issue or sell a senior security that is a stock unless certain requirements are met. Applicants state that the creation of multiple classes of shares of the Funds may violate section 18(a)(2) because the Funds may not meet such requirements with respect to a class of shares that may be a senior security.

2. Section 18(c) of the Act provides, in relevant part, that a closed-end investment company may not issue or sell any senior security if, immediately thereafter, the company has outstanding more than one class of senior security. Applicants state that the creation of multiple classes of shares of the Funds may be prohibited by section 18(c), as a class may have priority over another class as to payment of dividends because shareholders of different classes would pay different fees and expenses.

3. Section 18(i) of the Act provides that each share of stock issued by a registered management investment company will be a voting stock and have equal voting rights with every other outstanding voting stock. Applicants state that multiple classes of shares of the Funds may violate section 18(i) of the Act because each class would be entitled to exclusive voting rights with respect to matters solely related to that class.

4. Section 6(c) of the Act provides that the Commission may exempt any person, security or transaction or any class or classes of persons, securities or transactions from any provision of the Act, or from any rule or regulation under the Act, if and to the extent such

[3] Applicants submit that rule 23c–3 and Regulation M under the Exchange Act permit an interval fund to make repurchase offers to repurchase its shares while engaging in a continuous offering of its shares pursuant to Rule 415 under the Securities Act of 1933.

[4] Any reference to the FINRA Sales Charge Rule includes any successor or replacement to the FINRA Sales Charge Rule.

[5] *See* Shareholder Reports and Quarterly Portfolio Disclosure of Registered Management Investment Companies, Investment Company Act Release No. 26372 (Feb. 27, 2004) (adopting release) (requiring open-end investment companies to disclose fund expenses in shareholder reports); and Disclosure of Breakpoint Discounts by Mutual Funds, Investment Company Act Release No. 26464 (June 7, 2004) (adopting release) (requiring open-end investment companies to provide prospectus disclosure of certain sales load information).

[6] Fund of Funds Investments, Investment Company Act Rel. Nos. 26198 (Oct. 1, 2003) (proposing release) and 27399 (Jun. 20, 2006) (adopting release). See also Rules 12d1–1, *et seq.* of the Act.

exemption is necessary or appropriate in the public interest and consistent with the protection of investors and the purposes fairly intended by the policy and provisions of the Act. Applicants request an exemption under section 6(c) from sections 18(a)(2), 18(c) and 18(i) to permit the Funds to issue multiple classes of shares.

5. Applicants submit that the proposed allocation of expenses relating to distribution and voting rights among multiple classes is equitable and will not discriminate against any group or class of shareholders. Applicants submit that the proposed arrangements would permit a Fund to facilitate the distribution of its shares and provide investors with a broader choice of shareholder services. Applicants assert that the proposed closed-end investment company multiple class structure does not raise the concerns underlying section 18 of the Act to any greater degree than open-end investment companies' multiple class structures that are permitted by rule 18f–3 under the Act. Applicants state that each Fund will comply with the provisions of rule 18f–3 as if it were an open-end investment company.

Early Withdrawal Charges

1. Section 23(c) of the Act provides, in relevant part, that no registered closed-end investment company shall purchase securities of which it is the issuer, except: (a) On a securities exchange or other open market; (b) pursuant to tenders, after reasonable opportunity to submit tenders given to all holders of securities of the class to be purchased; or (c) under other circumstances as the Commission may permit by rules and regulations or orders for the protection of investors.

2. Rule 23c–3 under the Act permits a registered closed-end investment company (an ''interval fund'') to make repurchase offers of between five and twenty-five percent of its outstanding shares at net asset value at periodic intervals pursuant to a fundamental policy of the interval fund. Rule 23c–3(b)(1) under the Act permits an interval fund to deduct from repurchase proceeds only a repurchase fee, not to exceed two percent of the proceeds, that is paid to the interval fund and is reasonably intended to compensate the fund for expenses directly related to the repurchase.

3. Section 23(c)(3) provides that the Commission may issue an order that would permit a closed-end investment company to repurchase its shares in circumstances in which the repurchase is made in a manner or on a basis that does not unfairly discriminate against any holders of the class or classes of securities to be purchased.

4. Applicants request relief under section 6(c), discussed above, and section 23(c)(3) from rule 23c–3 to the extent necessary for the Funds to impose EWCs, which are distribution-related fees payable to the distributor, on shares of the Funds submitted for repurchase that have been held for less than a specified period.

5. Applicants state that the EWCs they intend to impose are functionally similar to CDSLs imposed by open-end investment companies under rule 6c–10 under the Act. Rule 6c–10 permits open-end investment companies to impose CDSLs, subject to certain conditions. Applicants note that rule 6c–10 is grounded in policy considerations supporting the employment of CDSLs where there are adequate safeguards for the investor and state that the same policy considerations support imposition of EWCs in the interval fund context. In addition, applicants state that EWCs may be necessary for the distributor to recover distribution costs. Applicants represent that any EWC imposed by the Funds will comply with rule 6c–10 under the Act as if the rule were applicable to closed-end investment companies. The Funds will disclose EWCs in accordance with the requirements of Form N–1A concerning CDSLs.

Asset-Based Distribution and/or Service Fees

1. Section 17(d) of the Act and rule 17d–1 under the Act prohibit an affiliated person of a registered investment company, or an affiliated person of such person, acting as principal, from participating in or effecting any transaction in connection with any joint enterprise or joint arrangement in which the investment company participates unless the Commission issues an order permitting the transaction. In reviewing applications submitted under section 17(d) and rule 17d–1, the Commission considers whether the participation of the investment company in a joint enterprise or joint arrangement is consistent with the provisions, policies and purposes of the Act, and the extent to which the participation is on a basis different from or less advantageous than that of other participants.

2. Rule 17d–3 under the Act provides an exemption from section 17(d) and rule 17d–1 to permit open-end investment companies to enter into distribution arrangements pursuant to rule 12b–1 under the Act. Applicants request an order under section 17(d) and rule 17d–1 under the Act to the extent necessary to permit the Fund to impose asset-based distribution and service fees. Applicants have agreed to comply with rules 12b–1 and 17d–3 as if those rules applied to closed–end investment companies, which they believe will resolve any concerns that might arise in connection with a Fund financing the distribution of its shares through asset-based distribution fees.

3. For the reasons stated above, applicants submit that the exemptions requested under section 6(c) are necessary and appropriate in the public interest and are consistent with the protection of investors and the purposes fairly intended by the policy and provisions of the Act. Applicants further submit that the relief requested pursuant to section 23(c)(3) will be consistent with the protection of investors and will insure that applicants do not unfairly discriminate against any holders of the class of securities to be purchased. Finally, applicants state that the Funds' imposition of asset-based distribution and/or service fees is consistent with the provisions, policies and purposes of the Act and does not involve participation on a basis different from or less advantageous than that of other participants.

Applicants' Condition

Applicants agree that any order granting the requested relief will be subject to the following condition:

Each Fund relying on the order will comply with the provisions of rules 6c–10, 12b–1, 17d–3, 18f–3, 22d–1, and, where applicable, 11a–3 under the Act, as amended from time to time, as if those rules applied to closed-end management investment companies, and will comply with the FINRA Sales Charge Rule, as amended from time to time, as if that rule applied to all closed-end management investment companies.

For the Commission, by the Division of Investment Management, under delegated authority.

Eduardo A. Aleman,

Assistant Secretary.

[FR Doc. 2017–16393 Filed 8–3–17; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Investment Company Act Release No. 32767; File No. 812–14733]

USQ Core Real Estate Fund and Union Square Capital Partners, LLC

July 31, 2017.

AGENCY: Securities and Exchange Commission (''Commission'').

ACTION: Notice.

Notice of an application under section 6(c) of the Investment Company Act of 1940 (the ''Act'') for an exemption from sections 18(a)(2), 18(c) and 18(i) of the Act, under sections 6(c) and 23(c) of the Act for an exemption from rule 23c–3 under the Act, and for an order pursuant to section 17(d) of the Act and rule 17d–1 under the Act.

Summary of Application: Applicants request an order to permit certain registered closed-end management investment companies to issue multiple classes of shares and to impose asset-based service and distribution fees, and early withdrawal charges (''EWCs'').

Applicants: USQ Core Real Estate Fund (the ''Fund'') and Union Square Capital Partners, LLC (the ''Adviser'').

Filing Dates: The application was filed on January 10, 2017 and amended June 8, 2017.

Hearing or Notification of Hearing: An order granting the requested relief will be issued unless the Commission orders a hearing. Interested persons may request a hearing by writing to the Commission's Secretary and serving applicants with a copy of the request, personally or by mail. Hearing requests should be received by the Commission by 5:30 p.m. on August 25, 2017, and should be accompanied by proof of service on the applicants, in the form of an affidavit, or, for lawyers, a certificate of service. Pursuant to rule 0–5 under the Act, hearing requests should state the nature of the writer's interest, any facts bearing upon the desirability of a hearing on the matter, the reason for the request, and the issues contested. Persons who wish to be notified of a hearing may request notification by writing to the Commission's Secretary.

ADDRESSES: Secretary, U.S. Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090; Applicants: USQ Core Real Estate Fund and Union Square Capital Partners, LLC, 235 Whitehorse Lane, Suite 200, Kennett Square, PA 19348.

FOR FURTHER INFORMATION CONTACT: Kieran G. Brown, Senior Counsel, at (202) 551–8707, or David Marcinkus, Branch Chief, at (202) 551–6821 (Division of Investment Management, Chief Counsel's Office).

SUPPLEMENTARY INFORMATION: The following is a summary of the application. The complete application may be obtained via the Commission's Web site by searching for the file number, or for an applicant using the Company name box, at *http://www.sec.gov/search/search.htm* or by calling (202) 551–8090.

Applicants' Representations

1. The Fund is a Delaware statutory trust that is registered under the Act as a non-diversified, closed-end management investment company. Applicants expect that the Fund's investment objective will be to generate a return comprised of both current income and capital appreciation with moderate volatility and low correlation to the broader markets.

2. The Adviser is a Delaware limited liability company and will register as an investment adviser under the Investment Advisers Act of 1940. The Adviser will serve as investment adviser to the Fund.

3. The applicants seek an order to permit the Fund to issue multiple classes of shares, each having its own fee and expense structure, and to impose asset-based distribution and service fees, and EWCs.

4. Applicants request that the order also apply to any continuously-offered registered closed-end management investment company that has been previously organized or that may be organized in the future for which the Adviser or any entity controlling, controlled by, or under common control with the Adviser, or any successor in interest to any such entity,[1] acts as investment adviser and which operates as an interval fund pursuant to rule 23c–3 under the Act or provides periodic liquidity with respect to its shares pursuant to rule 13e–4 under the Securities Exchange Act of 1934 (''Exchange Act'') (each, a ''Future Fund'' and together with the Fund, the ''Funds'').[2]

5. The Fund intends to make a continuous public offering of its shares following the effectiveness of its registration statement. Applicants state that additional offerings by any Fund relying on the order may be on a private placement or public offering basis. Shares of the Funds will not be listed on any securities exchange, nor quoted on any quotation medium. The Funds do not expect there to be a secondary trading market for their shares.

6. If the requested relief is granted, the Fund intends to offer an initial class of shares and may also offer additional classes of shares in the future, with each class having its own fee and expense structure. Because of the different distribution fees, services and any other class expenses that may be attributable to a class of a Fund's shares, the net income attributable to, and the dividends payable on, each class of shares may differ from each other.

7. Applicants state that, from time to time, Funds may create additional classes of shares, the terms of which may differ from the initial class in the following respects: (i) The amount of fees permitted by different distribution plans or different service fee arrangements; (ii) voting rights with respect to a distribution plan of a class; (iii) different class designations; (iv) the impact of any class expenses directly attributable to a particular class of shares allocated on a class basis as described in the application; (v) any differences in dividends and net asset value resulting from differences in fees under a distribution plan or service fee arrangement or in class expenses; (vi) any EWC or other sales load structure; and (vii) exchange or conversion privileges of the classes as permitted under the Act.

8. Applicants state that the Fund expects to adopt a fundamental policy to repurchase a specified percentage of its shares (no less than 5% and not more than 25%) at net asset value on a periodic basis. Such repurchase offers will be conducted pursuant to rule 23c–3 under the Act.[3] Each of the other Funds will likewise adopt a fundamental investment policy in compliance with rule 23c–3 and make periodic repurchase offers to its shareholders, or provide periodic liquidity with respect to its shares pursuant to rule 13e–4 under the Exchange Act. Any repurchase offers made by the Funds will be made to all holders of shares of each such Fund.

9. Applicants represent that any asset-based service and distribution fees for each class of shares will comply with the provisions of FINRA Rule 2341 (''Sales Charge Rule'').[4] Applicants also represent that each Fund will disclose in its prospectus the fees, expenses and other characteristics of each class of shares offered for sale by the prospectus, as is required for open-end multiple class funds under Form N–1A. As is required for open-end funds, each Fund will disclose its expenses in shareholder

[1] A successor in interest is limited to an entity that results from a reorganization into another jurisdiction or a change in the type of business organization.

[2] Any Fund relying on this relief in the future will do so in a manner consistent with the terms and conditions of the application. Applicants represent that each entity presently intending to rely on the requested relief is listed as an applicant.

[3] Applicants submit that rule 23c–3 and Regulation M under the Exchange Act permit an interval fund to make repurchase offers to repurchase its shares while engaging in a continuous offering of its shares pursuant to rule 415 under the Securities Act of 1933.

[4] Any reference to the Sales Charge Rule includes any successor or replacement rule that may be adopted by the Financial Industry Regulatory Authority (''FINRA'').

reports, and describe any arrangements that result in breakpoints in or elimination of sales loads in its prospectus.[5] In addition, applicants will comply with applicable enhanced fee disclosure requirements for fund of funds, including registered funds of hedge funds.[6]

10. Each of the Funds will comply with any requirements that the Commission or FINRA may adopt regarding disclosure at the point of sale and in transaction confirmations about the costs and conflicts of interest arising out of the distribution of open-end investment company shares, and regarding prospectus disclosure of sales loads and revenue sharing arrangements, as if those requirements applied to the Fund. In addition, each Fund will contractually require that any distributor of the Fund's shares comply with such requirements in connection with the distribution of such Fund's shares.

11. Each Fund will allocate all expenses incurred by it among the various classes of shares based on the net assets of the Fund attributable to each class, except that the net asset value and expenses of each class will reflect distribution fees, service fees, and any other incremental expenses of that class. Expenses of the Fund allocated to a particular class of shares will be borne on a pro rata basis by each outstanding share of that class. Applicants state that each Fund will comply with the provisions of rule 18f–3 under the Act as if it were an open-end investment company.

12. Applicants state that each Fund may impose an EWC on shares submitted for repurchase that have been held less than a specified period and may waive the EWC for certain categories of shareholders or transactions to be established from time to time. Applicants state that each of the Funds will apply the EWC (and any waivers or scheduled variations of the EWC) uniformly to all shareholders in a given class and consistently with the requirements of rule 22d–1 under the Act as if the Funds were open-end investment companies.

13. Each Fund operating as an interval fund pursuant to rule 23c–3 under the Act may offer its shareholders an exchange feature under which the shareholders of the Fund may, in connection with the Fund's periodic repurchase offers, exchange their shares of the Fund for shares of the same class of (i) registered open-end investment companies or (ii) other registered closed-end investment companies that comply with rule 23c–3 under the Act and continuously offer their shares at net asset value, that are in the Fund's group of investment companies (collectively, ''Other Funds''). Shares of a Fund operating pursuant to rule 23c–3 that are exchanged for shares of Other Funds will be included as part of the amount of the repurchase offer amount for such Fund as specified in rule 23c–3 under the Act. Any exchange option will comply with rule 11a–3 under the Act, as if the Fund were an open-end investment company subject to rule 11a–3. In complying with rule 11a–3, each Fund will treat an EWC as if it were a contingent deferred sales load (''CDSL'').

Applicants' Legal Analysis

Multiple Classes of Shares

1. Section 18(a)(2) of the Act makes it unlawful for a closed-end investment company to issue a senior security that is a stock unless (a) immediately after such issuance it will have an asset coverage of at least 200% and (b) provision is made to prohibit the declaration of any distribution, upon its common stock, or the purchase of any such common stock, unless in every such case such senior security has at the time of the declaration of any such distribution, or at the time of any such purchase, an asset coverage of at least 200% after deducting the amount of such distribution or purchase price, as the case may be. Applicants state that the creation of multiple classes of shares of the Funds may violate section 18(a)(2) because the Funds may not meet such requirements with respect to a class of shares that may be a senior security.

2. Section 18(c) of the Act provides, in relevant part, that a closed-end investment company may not issue or sell any senior security if, immediately thereafter, the company has outstanding more than one class of senior security. Applicants state that the creation of multiple classes of shares of the Funds may be prohibited by section 18(c), as a class may have priority over another class as to payment of dividends because shareholders of different classes would pay different fees and expenses.

3. Section 18(i) of the Act provides that each share of stock issued by a registered management investment company will be a voting stock and have equal voting rights with every other outstanding voting stock. Applicants state that multiple classes of shares of the Funds may violate section 18(i) of the Act because each class would be entitled to exclusive voting rights with respect to matters solely related to that class.

4. Section 6(c) of the Act provides that the Commission may exempt any person, security or transaction or any class or classes of persons, securities or transactions from any provision of the Act, or from any rule or regulation under the Act, if and to the extent such exemption is necessary or appropriate in the public interest and consistent with the protection of investors and the purposes fairly intended by the policy and provisions of the Act. Applicants request an exemption under section 6(c) from sections 18(a)(2), 18(c) and 18(i) to permit the Funds to issue multiple classes of shares.

5. Applicants submit that the proposed allocation of expenses relating to distribution and voting rights among multiple classes is equitable and will not discriminate against any group or class of shareholders. Applicants submit that the proposed arrangements would permit a Fund to facilitate the distribution of its shares and provide investors with a broader choice of shareholder services. Applicants assert that the proposed closed-end investment company multiple class structure does not raise the concerns underlying section 18 of the Act to any greater degree than open-end investment companies' multiple class structures that are permitted by rule 18f–3 under the Act. Applicants state that each Fund will comply with the provisions of rule 18f–3 as if it were an open-end investment company.

Early Withdrawal Charges

1. Section 23(c) of the Act provides, in relevant part, that no registered closed-end investment company shall purchase securities of which it is the issuer, except: (a) On a securities exchange or other open market; (b) pursuant to tenders, after reasonable opportunity to submit tenders given to all holders of securities of the class to be purchased; or (c) under other circumstances as the Commission may permit by rules and regulations or orders for the protection of investors.

2. Rule 23c–3 under the Act permits a registered closed-end investment

[5] *See* Shareholder Reports and Quarterly Portfolio Disclosure of Registered Management Investment Companies, Investment Company Act Release No. 26372 (Feb. 27, 2004) (adopting release) (requiring open-end investment companies to disclose fund expenses in shareholder reports); and Disclosure of Breakpoint Discounts by Mutual Funds, Investment Company Act Release No. 26464 (June 7, 2004) (adopting release) (requiring open-end investment companies to provide prospectus disclosure of certain sales load information).

[6] Fund of Funds Investments, Investment Company Act Rel. Nos. 26198 (Oct. 1, 2003) (proposing release) and 27399 (Jun. 20, 2006) (adopting release). *See* also Rules 12d1–1, *et seq.* of the Act.

company (an ''interval fund'') to make repurchase offers of between five and twenty-five percent of its outstanding shares at net asset value at periodic intervals pursuant to a fundamental policy of the interval fund. Rule 23c–3(b)(1) under the Act permits an interval fund to deduct from repurchase proceeds only a repurchase fee, not to exceed two percent of the proceeds, that is paid to the interval fund and is reasonably intended to compensate the fund for expenses directly related to the repurchase. A Fund will not impose a repurchase fee on investors who purchase and tender their shares.

3. Section 23(c)(3) provides that the Commission may issue an order that would permit a closed-end investment company to repurchase its shares in circumstances in which the repurchase is made in a manner or on a basis that does not unfairly discriminate against any holders of the class or classes of securities to be purchased.

4. Applicants request relief under section 6(c), discussed above, and section 23(c)(3) from rule 23c–3 to the extent necessary for the Funds to impose EWCs on shares of the Funds submitted for repurchase that have been held for less than a specified period.

5. Applicants state that the EWCs they intend to impose are functionally similar to CDSLs imposed by open-end investment companies under rule 6c–10 under the Act. Rule 6c–10 permits open-end investment companies to impose CDSLs, subject to certain conditions. Applicants note that rule 6c–10 is grounded in policy considerations supporting the employment of CDSLs where there are adequate safeguards for the investor and state that the same policy considerations support imposition of EWCs in the interval fund context. In addition, applicants state that EWCs may be necessary for the distributor to recover distribution costs. Applicants represent that any EWC imposed by the Funds will comply with rule 6c–10 under the Act as if the rule were applicable to closed-end investment companies. The Funds will disclose EWCs in accordance with the requirements of Form N–1A concerning CDSLs.

Asset-Based Service and Distribution Fees

1. Section 17(d) of the Act and rule 17d–1 under the Act prohibit an affiliated person of a registered investment company, or an affiliated person of such person, acting as principal, from participating in or effecting any transaction in connection with any joint enterprise or joint arrangement in which the investment company participates unless the Commission issues an order permitting the transaction. In reviewing applications submitted under section 17(d) and rule 17d–1, the Commission considers whether the participation of the investment company in a joint enterprise or joint arrangement is consistent with the provisions, policies and purposes of the Act, and the extent to which the participation is on a basis different from or less advantageous than that of other participants.

2. Rule 17d–3 under the Act provides an exemption from section 17(d) and rule 17d–1 to permit open-end investment companies to enter into distribution arrangements pursuant to rule 12b–1 under the Act. Applicants request an order under section 17(d) and rule 17d–1 under the Act to the extent necessary to permit the Funds to impose asset-based service and distribution fees. Applicants have agreed to comply with rules 12b–1 and 17d–3 as if those rules applied to closed-end investment companies, which they believe will resolve any concerns that might arise in connection with a Fund financing the distribution of its shares through asset-based service and distribution fees.

3. For the reasons stated above, applicants submit that the exemptions requested under section 6(c) are necessary and appropriate in the public interest and are consistent with the protection of investors and the purposes fairly intended by the policy and provisions of the Act. Applicants further submit that the relief requested pursuant to section 23(c)(3) will be consistent with the protection of investors and will insure that applicants do not unfairly discriminate against any holders of the class of securities to be purchased. Finally, applicants state that the Funds' imposition of asset-based service and distribution fees is consistent with the provisions, policies and purposes of the Act and does not involve participation on a basis different from or less advantageous than that of other participants.

Applicants' Condition

Applicants agree that any order granting the requested relief will be subject to the following condition:

Each Fund relying on the order will comply with the provisions of rules 6c–10, 12b–1, 17d–3, 18f–3, 22d–1, and, where applicable, 11a–3 under the Act, as amended from time to time, as if those rules applied to closed-end management investment companies, and will comply with the Sales Charge Rule, as amended from time to time, as if that rule applied to all closed-end management investment companies.

For the Commission, by the Division of Investment Management, under delegated authority.

Eduardo A. Aleman,

Assistant Secretary.

[FR Doc. 2017–16392 Filed 8–3–17; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–81263; File No. SR–ISE–2017–32]

Self-Regulatory Organizations; Nasdaq ISE, LLC; Notice of Filing of Amendment No. 1 and Order Granting Accelerated Approval of a Proposed Rule Change, as Modified by Amendment No. 1 Thereto, To Harmonize the Corporate Governance Framework of Nasdaq ISE, LLC With That of The NASDAQ Stock Market LLC, NASDAQ PHLX LLC, and NASDAQ BX, Inc.

July 31, 2017.

I. Introduction

On April 11, 2017, Nasdaq ISE, LLC (''ISE'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission''), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder,[2] proposed rule changes to its corporate governance documents and trading rules to align its corporate governance framework to the structure of other exchanges owned by its ultimate parent company, Nasdaq, Inc. The proposed rule change was published for comment in the **Federal Register** on May 2, 2017.[3] The Commission received no comments on the proposal. On June 14, 2017, the Commission extended the time period within which to approve the proposed rule change, disapprove the proposed rule change, or institute proceedings to determine whether to disapprove the proposed rule change.[4] On July 6, 2017, the Exchange filed Amendment No. 1 to the proposed rule change.[5] The

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 80530 (April 26, 2017), 82 FR 20508 (''Notice'').

[4] *See* Securities Exchange Act Release No. 80923, 82 FR 28102 (June 20, 2017).

[5] As discussed further herein, Amendment No. 1, which replaces the original filing in its entirety, includes, among other things: (1) Changes to the Exchange's proposed Limited Liability Company Agreement (''New LLC Agreement'') and proposed By-Laws (''New By-Laws,'' and together with the New LLC Agreement, the ''New Governing Documents'') to better align these proposed documents with certain provisions in ISE's existing governing documents and the governing documents

Continued

Commission is publishing this notice to solicit comment on Amendment No. 1 from interested persons and is approving the proposed rule change, as modified by Amendment No. 1, on an accelerated basis.

II. Background

On June 21, 2016, the Commission approved a proposed rule change relating to a corporate transaction in which Nasdaq, Inc. would become the ultimate parent of ISE (the ''Nasdaq Acquisition''), Nasdaq GEMX, LLC (''GEMX''), and Nasdaq MRX, LLC (''MRX,'' and together with ISE and GEMX, the ''ISE Exchanges'').[6] On June 30, 2016, pursuant to this transaction, Nasdaq, Inc. acquired all of the capital stock of U.S. Exchange Holdings, Inc. (''Exchange Holdings''), and thereby became the indirect, ultimate parent of the ISE Exchanges.[7] Nasdaq, Inc. is also the ultimate parent of NASDAQ BX, Inc. (''BX''), The NASDAQ Stock Market LLC (''Nasdaq''), and NASDAQ PHLX LLC (''Phlx'' and, together with Nasdaq and BX, the ''Nasdaq Exchanges'').[8] The Commission notes that the corporate governance documents of ISE, specifically its Third Amended and Restated Limited Liability Company Agreement (''Current LLC Agreement'') and its Second Amended and Restated Constitution (''Current Constitution'' and, together with the Current LLC Agreement, the ''Current Governing Documents'') are rules of the Exchange,[9] as are the governing documents of ISE's Upstream Owners,[10] which include certain provisions that are designed to maintain the independence of ISE's self-regulatory functions (as well as the self-regulatory functions of the Upstream Owners' other self-regulatory subsidiaries, *i.e.,* the Nasdaq Exchanges).[11]

The Exchange intends to effect a merger with a newly-formed Delaware limited liability company (''Merger'') under Nasdaq, Inc. that would result in ISE as the surviving entity with new corporate governance documents. In connection with that Merger, the Exchange proposes various changes to its corporate governance documents and rules (''Rules'').[12] Specifically, the Exchange proposes to: (1) Delete the Exchange's Current LLC Agreement in its entirety and replace it with the New LLC Agreement, which is based on the limited liability company agreement of Nasdaq; [13] (2) delete the Exchange's Current Constitution in its entirety and replace it with the New By-Laws, which are based on the by-laws of Nasdaq; [14] and (3) amend certain of its Rules to reflect the replacement of the Current Governing Documents with the New Governing Documents.[15]

The Exchange represents that the proposed changes are designed to align the Exchange's corporate governance framework with the existing structure of the Nasdaq Exchanges, particularly as it relates to the board and committee structure, nomination and election processes, and related governance practices.[16] The Exchange also represents that it is not proposing any amendments to its ownership structure. The Exchange does not propose any amendments to the governing documents of its Upstream Owners.[17] Thus, the provisions in the governing documents of these entities, which were designed to maintain the independence of ISE's self-regulatory functions, would remain unchanged. The Exchange also represents that it is not proposing any amendments to its Rules at this time, other than to reflect the changes to its governing documents as described in more detail below.[18] The Exchange states that it intends to implement its proposed rule change no later than by the end of the third quarter of 2017.[19]

III. Discussion and Commission Findings

After careful review, the Commission finds that the proposed rule change, as modified by Amendment No. 1, is consistent with the requirements of the Act and the rules and regulations thereunder applicable to a national securities exchange.[20] Specifically, as discussed in more detail below, the Commission finds that the proposed rule change is consistent with Sections 6(b)(1) and 6(b)(3) of the Act,[21] which require, among other things, that a national securities exchange be so organized and have the capacity to carry out the purposes of the Act, and to comply and enforce compliance by its members and persons associated with its members, with the provisions of the Act, the rules and regulations thereunder, and the rules of the exchange, and assure the fair representation of its members and persons associated with its members in the selection of its directors and administration of its affairs, and provide that one or more directors shall be representative of issuers and investors and not be associated with a member of the exchange, broker, or dealer. Further, the Commission finds that the proposed rule change is consistent with Section 6(b)(5) of the Act,[22] which requires,

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of other exchanges, including provisions concerning limitations on board committee powers, the confidentiality of books and records, the nomination of certain board directors by petition, and the confidentiality of board meetings pertaining to the Exchange's self-regulatory functions; (2) revisions to the proposed amendments to ISE's rules regarding ownership, voting, and transfer restrictions relating to certain market maker rights on the Exchange; (3) revisions to the related discussion of the purpose of the proposed changes; (4) clarification of certain aspects of the proposed rule changes (*e.g.,* the nomination of Member Representative members to committees; and certain market maker rights and their related ownership, voting, and transfer restrictions); and (5) certain technical corrections (*e.g.,* correcting incorrect cross references to Exhibits 5A, 5B, 5C, and 5D, updating the proposed implementation date and the description of the Exchange's most recent annual election of its board, and amending the proposed New LLC Agreement to reflect the current address of the Exchange and its Sole LLC Member). When the Exchange filed Amendment No. 1 with the Commission, it also submitted Amendment No. 1 to the public comment file for SR–ISE–2017–32 (*available at: https://www.sec.gov/comments/sr-ise-2017-32/ise201732.htm*).

[6] *See* Securities Exchange Act Release No. 78119 (June 21, 2016), 81 FR 41611 (June 27, 2016) (SR–ISE–2016–11; SR–ISEGemini–2016–05; SR–ISEMercury–2016–10) (''Nasdaq Acquisition Order'') (order approving Nasdaq, Inc.'s acquisition of ISE, GEMX (f/k/a ISE Gemini, LLC), and MRX (f/k/a ISE Mercury, LLC)).

[7] *See* Notice, *supra* note 3, at 20508 n.3. Exchange Holdings is the sole owner of ISE Holdings, Inc. (''ISE Holdings,'' and together with Exchange Holdings and Nasdaq, Inc., the ''Upstream Owners''), which is the sole owner of 100% of the Exchange's limited liability company interests. *See* Notice, *supra* note 3, at 20508–09; *see also* Nasdaq Acquisition Order, *supra* note 6, at 41611. ISE Holdings is also the sole direct owner of GEMX and MRX. *See* Nasdaq Acquisition Order, *supra* note 6, at 41611.

[8] *See* Notice, *supra* note 3, at 20508. *See also* Nasdaq Acquisition Order, *supra* note 6, at 41611. As a result of this transaction, the ISE Exchanges and the Nasdaq Exchanges became affiliates. *See* Nasdaq Acquisition Order, *supra* note 6, at 41611 n.8.

[9] *See* Securities Exchange Act Release No. 53705 (April 21, 2006), 71 FR 25260, 25262–63 (April 28, 2006) (''ISE HoldCo Order'') (order approving SR–ISE–2006–04).

[10] *See* Nasdaq Acquisition Order, *supra* note 6, at 41612; Securities Exchange Act Release No. 56955 (December 13, 2007), 72 FR 71979, 71981–82 (December 19, 2007) (order approving SR–ISE–2007–101); ISE HoldCo Order, *supra* note 9, at 25262.

[11] *See, e.g.,* Nasdaq Acquisition Order, *supra* note 6, at 41612–13; ISE HoldCo Order, *supra* note 9, at 25264.

[12] The Rules as proposed to be amended pursuant to the proposed rule change are referred to herein as the ''New Rules.''

[13] *See* Notice, *supra* note 3, at 20508 n.5.

[14] *Id.*

[15] The Exchange states that its affiliates, GEMX and MRX, will submit nearly identical proposed rule changes. *See* Notice, *supra* note 3, at 20508 n.4.

[16] *See id.* at 20508.

[17] *See generally id.;* Amendment No. 1.

[18] *See* Notice, *supra* note 3, at 20509 and 20522. *See also* Amendment No. 1.

[19] *See* Amendment No. 1. The Exchange also states that it will alert its members in the form of a regulatory alert to provide notification of the implementation date. *Id.*

[20] In approving these proposed rule changes, the Commission has considered the proposed rules' impact on efficiency, competition and capital formation. 15 U.S.C. 78c(f).

[21] 15 U.S.C. 78f(b)(1) and (b)(3).

[22] 15 U.S.C. 78f(b)(5).

among other things, that the rules of a national securities exchange be designed to prevent fraudulent and manipulative acts and practices; to promote just and equitable principles of trade; to foster cooperation and coordination with persons engaged in regulating, clearing, settling, and processing information with respect to, and facilitating transactions in securities; to remove impediments to and perfect the mechanism of a free and open market and a national market system; and, in general, to protect investors and the public interest.

A. Ownership of the Exchange

ISE is currently structured as a Delaware limited liability company (''Delaware LLC'') [23] and, as discussed above, is a wholly-owned subsidiary of ISE Holdings. ISE Holdings, in turn is a wholly-owned subsidiary of Exchange Holdings, which is wholly-owned by Nasdaq, Inc. Pursuant to the Current LLC Agreement, ISE Holdings is defined as the Sole LLC Member.[24] As the Sole LLC Member, ISE Holdings may assign all (but not less than all) of its interest in the Exchange, subject to prior approval by the Commission pursuant to the rule filing procedures under Section 19 of the Act.[25]

Pursuant to the proposed rule change, ISE will be merged with a newly formed Delaware LLC, whereby ISE will be the surviving entity, governed by the New Governing Documents. ISE Holdings will continue to be the direct owner of ISE and will be defined as the ''Company Member'' or ''Sole LLC Member'' in the New LLC Agreement and New By-Laws.[26] Additionally, pursuant to the New LLC Agreement, ISE Holdings will not be permitted to assign, in whole or in part, its limited liability company interest in the Exchange, unless such transfer or assignment is filed with and approved by the Commission pursuant to the rule filing procedures under Section 19 of the Act.[27]

The Commission believes that the proposed restrictions on ISE Holdings' assignment of its ownership interest in ISE, taken together with restrictions on voting and ownership limitations in the governing documents of ISE's Upstream Owners that were previously approved by the Commission,[28] are designed to minimize the potential that a person could improperly interfere with, or restrict the ability of, the Commission or ISE to effectively carry out its regulatory oversight responsibilities under the Act. The Commission also notes that the restrictions on transfer of ownership interest in the Exchange will be similar to those currently in place. In this regard, the Commission believes the proposed rule change is consistent with Section 6(b)(1) of the Act [29] in particular, which requires that an exchange be organized and have the capacity to be able to carry out the purposes of the Act and to comply, and to enforce compliance by its members and persons associated with its members, with the provisions of the Act, the rules and regulations thereunder, and the rules of the exchange.

B. Governance of the Exchange

With the replacement of the Current Governing Documents with the New Governing Documents, the Exchange proposes to replace certain provisions pertaining to governance of the Exchange with related provisions that are based on provisions currently in the Nasdaq LLC Agreement and Nasdaq By-Laws.[30] These changes include, among others, provisions governing: the composition of the Exchange's board of directors (''Board'' or ''Board of Directors,'' and each member of the Board of Directors a ''Director''); the process for nominating, electing, and removing Directors; the filling of vacancies on the Exchange's Board; its board committee structure; and regulatory independence of the Exchange.[31] As noted above, the Exchange intends that the New Governing Documents would be implemented no later than by the end of the third quarter of 2017.[32]

1. Board of Directors: Powers and Composition

Under the New Governing Documents and consistent with the Current LLC Agreement,[33] the business and affairs of the Exchange will be managed under the discretion of its Board, which will be vested with the power to do any and all acts necessary or for the furtherance of the purposes described in the New LLC Agreement, including fulfilling the Exchange's self-regulatory responsibilities as set forth in the Act.[34] The new Board will also have the power to bind the Exchange and delegate powers,[35] as it does today.[36]

ISE Holdings, as the Sole LLC Member, may determine at any time, in its sole and absolute discretion, the number of Directors to constitute the Board of Directors.[37] At least 20% of the Directors shall be ''Member Representative Directors.'' [38] Additionally, the Board of Directors must include a number of ''Non-Industry Directors,'' including at least one ''Public Director'' and at least one ''issuer representative'' (or if the Board consists of ten or more Directors, at least two issuer representatives), that equals or exceeds the sum of the number of Industry Directors and Member Representative Directors.[39]

[23] *See* Current LLC Agreement.

[24] *See id.* The Current Constitution also defines ISE Holdings as the Sole LLC Member of the Exchange and permits assignment of its LLC interest as provided in the Current LLC Agreement. *See* Current Constitution, Section 1.1.

[25] *See* Current LLC Agreement, Section 7.1.

[26] *See* New LLC Agreement, Schedule A; and New By-Laws, Article I(f).

[27] *See* New LLC Agreement, Section 20. Pursuant to Section 7.1 of the Current LLC Agreement, ISE Holdings may only assign all (but not less than all) of its ownership interest, and any assignment of ISE Holdings' interest in ISE would similarly be subject to approval by the Commission pursuant to the rule filing procedures under Section 19 of the Act.

[28] *See* Nasdaq Acquisition Order, *supra* note 6, at 41612–17 (discussing provisions, including voting and ownership limitations, in the governing documents of Nasdaq, Inc. and other Upstream Owners that are designed to maintain the independence of their self-regulatory subsidiaries); ISE HoldCo Order, *supra* note 9, at 25262–63 (discussing voting and ownership limitations in the governing documents of ISE Holdings); *see also* Securities Exchange Act Release No. 76998 (January 29, 2016), 81 FR 6066, 6067, 6069, 6071–73 (February 4, 2016) (''Mercury Exchange Approval'') (approving the registration of ISE Mercury, LLC as a national securities exchange and discussing the provisions in the governing documents of ISE Holdings and other Upstream Owners that are designed to preserve the self-regulatory function of the national securities exchanges they control, which includes ISE).

[29] 15 U.S.C. 78(b)(1).

[30] *See* Notice, *supra* note 3, at 20514–17; and Amendment No. 1.

[31] *See* Notice, *supra* note 3, at 20514–17; and Amendment No. 1.

[32] *See supra* note 19 and accompanying text.

[33] *See* Current LLC Agreement, Article II, Section 2.2 and Article V, Sections 5.1 and 5.7; and Current Constitution, Article III, Section 3.1.

[34] *See* New LLC Agreement, Sections 7, 8, and 9(a).

[35] *See* New LLC Agreement, Section 9(b).

[36] *See* Current LLC Agreement, Article II, Section 2.2; and Current Constitution, Article V, Section 5.1.

[37] *See* New LLC Agreement, Section 9(a).

[38] *See id.* A ''Member Representative Director'' will be defined as a Director who has been elected or appointed after having been nominated by the Member Nominating Committee or by an Exchange Member pursuant to the New By-Laws and may be, but is not required to be, an officer, director, employee, or agent of an Exchange Member. *See* New By-Laws, Article I(r).

[39] *See* New By-Laws, Article III, Section 2(a). A ''Non-Industry Director'' will be defined as a Director (excluding an officer of the Exchange serving as a Director (''Staff Director'')) who is (i) a Public Director; (ii) an officer, director, or employee of an issuer of securities listed on the Exchange; or (iii) any other individual who would not be an Industry Director. *See* New By-Laws, Article I(w). A ''Public Director'' will be defined as a Director who has no material business relationship with a broker or dealer, the Exchange or its affiliates, or FINRA. *See* New By-Laws, Article I(z). An ''Industry Director'' will be defined as a

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Additionally, up to two Staff Directors [40] may be elected to the Board.[41] A Director may not be subject to a statutory disqualification.[42] A Director will be removed upon a determination by the Board, by a majority vote of the remaining Directors, that the Director no longer satisfies the classification for which the Director was elected and that the Director's continued service on the Board would violate the board composition requirements.[43]

As discussed in more detail below,[44] the current Board was elected at the Exchange's 2017 annual election of its Board (the ''2017 Annual Election,'' and such Board the ''2017 Board''), which was held on June 19, 2017, pursuant to the Current Governing Documents. When the New Governing Documents become operative, the 2017 Board will appoint a Nominating Committee and a Member Nominating Committee.[45] The Member Nominating Committee will nominate candidates for each Member Representative Director position on the Board,[46] as well as nominate candidates for appointment by the Board for each vacant or new position on a committee that is to be filled with a ''Member Representative member'' [47] under the New By-Laws.[48] If an Exchange Member [49] submits a timely and duly executed written nomination to the Secretary of the Exchange, additional candidates may be added to the List of Candidates [50] for the Member Representative Director positions.[51] These candidates, together with candidates nominated by the Member Nominating Committee, will then be presented to Exchange Members for election.[52] The Nominating Committee will nominate candidates for all other vacant or new Director positions on the Board.[53]

The Commission believes that the proposed composition of the Exchange's Board satisfies the requirements in Section 6(b)(3) of the Act,[54] which requires in part that one or more directors be representative of issuers and investors and not be associated with a member of the exchange, or with a broker or dealer.[55] The Commission previously has stated that the inclusion of public, non-industry representatives on exchange oversight bodies is an important mechanism to support an exchange's ability to protect the public interest,[56] and that they can help to ensure that no single group of market participants has the ability to systematically disadvantage others through the exchange governance

Director with direct ties to the securities industry as a result of connections to a broker-dealer, the Exchange or its affiliates, FINRA, or certain service providers to such entities. *See* Notice, *supra* note 3, at 20516 n.69. *See also* New By-Laws, Article I(m).

[40] *See* New By-Laws, Article I(m); *see also* Notice, *supra* note 3, at 20516 n.72 and accompanying text.

[41] *See* Current LLC Agreement, Article II, Section 2.2.

[42] *See* New LLC Agreement, Section 9(a).

[43] *See* New By-Laws, Article III, Section 2(b). If the remaining term of office of a removed Director is not more than six months, the Board will not be deemed to be in violation of the Article III, Section 2(a) composition requirements during the vacancy by virtue of such vacancy. *See id.*

[44] *See infra* notes 65–68, 70–71, and accompanying text.

[45] *See* Notice, *supra* note 3, at 20517. The Nominating Committee will consist of no fewer than six and no more than nine members. The number of Non-Industry members on the Nominating Committee shall equal or exceed the number of Industry members on the Nominating Committee. If the Nominating Committee consists of six members, at least two shall be Public members, and if the Nominating Committee consists of seven or more members, at least three shall be Public members. The Member Nominating Committee shall consist of no fewer than three and no more than six members. All members of the Member Nominating Committee shall be a current associated person of a current Exchange Member, and the Board will appoint such individuals after appropriate consultation with representatives of Exchange Members. *See* New By-Laws, Article III, Sections 6(b)(i) and (iii). *See also* Notice, *supra* note 3, at 20520–21 (discussing the compositional requirements for, and responsibilities of, the Nominating Committee and Member Nominating Committee).

An ''Industry member'' will be a member of any committee appointed by the Board that is associated with a broker-dealer as defined in the New By-Laws, Article I(n). A ''Non-Industry member'' will be defined as a member of any committee appointed by the Board who is (i) a Public member; (ii) an officer or employee of an issuer of securities listed on the Exchange; or (iii) any other individual who would not be an Industry member. *See* New By-Laws, Article I(x). A ''Public member'' will be defined as a member of any committee appointed by the Board who has no material business relationship with a broker or dealer, the Company or its affiliates, or FINRA. *See* New By-Laws, Article I(aa).

[46] Pursuant to the New By-Laws, Member Representative Directors shall be elected to the Board on an annual basis. *See* New By-Laws, Article II, Section 1(a).

[47] Pursuant to the New By-Laws, a ''Member Representative member'' will be defined as a member of any committee appointed by the Board who has been elected or appointed after having been nominated by the Member Nominating Committee pursuant to the By-Laws. *See* New By-Laws, Article I(s). As discussed further below, the required inclusion of such representatives on certain committees, and the process by which they are to be selected, is designed to comply with the fair representation requirements of Section 6(b)(3) of the Act. *See infra* note 102 and accompanying text. *See also* Amendment No. 1.

In Amendment No. 1, the Exchange clarifies the description of the functions of the Member Nominating Committee. Specifically, the Exchange clarifies that the new Member Nominating Committee is responsible for: (i) The nomination for election of Member Representative Directors to the Board and (ii) the nomination for appointment of Member Representative members to the committees requiring such members. *See* Amendment No. 1.

[48] *See* New By-Laws, Article III, Section 6(b).

[49] ''Exchange Member'' will be defined as any registered broker or dealer that has been admitted to membership in the national securities exchange operated by ISE. *See* New By-Laws, Article 1(u).

[50] ''List of Candidates'' will be defined as the list of candidates for Member Representative Director positions to be elected on an Election Date. *See* New By-Laws, Article 1(p).

''Election Date≥ will be defined as a date selected by the Board on an annual basis, on which Exchange Members may vote with respect to Member Representative Directors in the event of a Contested Election. *See* New By-Laws, Article 1(k). *See also infra* note 52, for the definition of ''Contested Election.''

[51] *See* New By-Laws, Article II, Section 1(b). *See also* Amendment No. 1.

[52] If there is only one candidate for each Member Representative Director position to be elected on the annual election date, the Member Representative Directors shall be elected by ISE Holdings as the Sole LLC Member. If, as a result of the nomination and petition process, there are more Member Representative Directors candidates than the number of positions to be elected, each Exchange Member shall have the right to cast one vote for each Member Representative Director, and the candidates who receive the most votes shall be elected to the Member Representative Director positions. An Exchange Member, however, either alone or together with its affiliates, may not cast votes representing more than 20% of the votes cast for a candidate. *See* New By-Laws, Article II, Section 1(c) and Section 2. *See also* New By-Laws, Article 1(g) (defining ''Contested Election'' as an election for one or more Member Representative Directors for which the number of candidates on the List of Candidates exceeds the number of positions to be elected).

Under the Exchange's Current Governing Documents, six directors on the Board are officers, directors, or partners of Exchange members, and are elected by a plurality of the holders of Exchange Rights (''Exchange Directors''), of which two must be elected by holders of PMM Rights, two must be elected by holders of CMM Rights, and two must be elected by holders of EAM Rights. *See* Notice, *supra* note 3, at 20510. *See also* Current Constitution, Article III, Section 3.2. The Exchange states that this current structure was adopted to comply with the fair representation requirements of Section 6(b) of the Act. *See* Notice, *supra* note 3, at 20510. Because they give members a voice in the Exchange's use of its self-regulatory authority, the Exchange believes that Exchange Directors serve the same function as Member Representative Directors on the boards of the Nasdaq Exchanges. *See id.*

The Exchange notes that the Commission has previously found the Nasdaq LLC Agreement's (1) 20% Member Representative Director requirement, and (2) election process, provide fair representation of Nasdaq members, consistent with the requirements of Section 6(b) of the Act. *See* Notice, *supra* note 3, at 20510 n.18 (citing Securities Exchange Act Release No. 53128 (January 13, 2006), 71 FR 3550, 3553 (January 23, 2006) (''Nasdaq Exchange Order'') (granting the exchange registration of Nasdaq Stock Market, Inc.). The Commission notes that the Board compositional requirements and the process for electing Member Representative Directors in the New Governing Documents are based on the parallel requirements in the Nasdaq LLC Agreement.

[53] *See* New By-Laws, Article III, Section 6(b).

[54] 15 U.S.C. 78f(b)(3).

[55] The Commission also notes that it previously found the compositional requirements for the board of directors of Nasdaq, upon which ISE's proposed requirements are based, to be consistent with Act. *See* Nasdaq Exchange Order, *supra* note 52, at 3553.

[56] *See, e.g.,* Regulation of Exchanges and Alternative Trading Systems, Securities Exchange Act Release No. 40760 (December 8, 1998), 63 FR 70844 (December 22, 1998) (''Regulation ATS Release'').

process.[57] As it has previously stated, the Commission believes that public directors can provide unbiased perspectives, which may enhance the ability of the Board to address issues in a non-discriminatory fashion and foster the integrity of the Exchange.[58]

The Commission also believes that the proposed requirement that at least 20% of the Directors be Member Representative Directors, and the means by which they will be chosen by Exchange Members, is consistent with Section 6(b)(3) of the Act,[59] because it provides for the fair representation of members in the selection of directors and the administration of ISE. Section 6(b)(3) of the Act requires that ''the rules of the exchange assure a fair representation of its members in the selection of its directors and administration of its affairs and provide that one or more directors shall be representative of issuers and investors and not be associated with a member of the exchange, broker, or dealer.'' [60] As the Commission previously has noted, this statutory requirement helps to ensure that members have a voice in the Exchange's use of its self-regulatory authority, and that the Exchange is administered in a way that is equitable to all those persons who trade on its markets or through its facilities.[61] In addition, the Commission believes that the requirement that at least one director be a Public Director and one an issuer representative satisfies the requirements of Section 6(b)(3) of the Act.[62]

2. Transition From Current Board Election Process to the New Election Process

In its filing, the Exchange states that, when it was acquired by Nasdaq, Inc., there were a number of harmonizing changes to its Board that resulted in a complete overlap of directors on the ISE Boards and the Nasdaq Exchanges (the ''Post-Acquisition Board'').[63] ISE also states its belief that the Post-Acquisition Board satisfied the composition requirements contained in both the Current Constitution and the New By-Laws.[64] The Exchange states that the terms of the Directors on the Post-Acquisition Board ended at the 2017 Annual Election,[65] and that all of the Directors on the 2017 Board are Directors that served on the Post-Acquisition Board. The Exchange believes that the 2017 Board satisfies both the board composition requirements in the Current Governing Documents, as well as in the New Governing Documents,[66] and that once the New Governing Documents become operative, no additional actions with respect to the 2017 Board will be required under the Delaware Limited Liability Company Act.[67] Pursuant to the proposal, the 2017 Board will serve until the Exchange's first annual election of Directors in accordance with the processes under the New Governing Documents in 2018 (''2018 Board'').[68]

The Commission believes the Exchange's proposal to allow the 2017 Board to continue serving until the 2018 Board would be elected pursuant to the process in the New Governing Documents is consistent with the Act, and in particular Section 6(b)(3) of the Act.[69] The Exchange states that, although the 2017 Board was not nominated or voted upon in accordance with the New Governing Documents, it believes that the composition of the 2017 Board is consistent with the Act, as it still provides for the fair representation of members and has one or more directors that are representative of issuers and investors and not associated with a member of the exchange, broker, or dealer. Specifically, the Exchange states that six Directors are officers, directors, or partners of Exchange members, as required by Section 3.2(b) of the Current Constitution, and were elected by a plurality of the holders of ''Exchange Rights.'' [70] These Exchange Directors were subject to the full petition and voting process by membership in accordance with Articles II and III of the Current Constitution, which process the Commission previously found to satisfy the requirements of the Act.[71] The Exchange believes that the Exchange Directors serve the same function as the Member Representative Directors under the proposed board structure, as both directorships give Exchange members a voice in the Exchange's use of its self-regulatory authority.[72] The Exchange also notes that only its corporate governance structure would change under the proposed rule change, and that its membership has remained substantially the same both before and after the 2017 Annual Election.[73] Additionally, the Commission notes that, under the Current Governing Documents, the 2017 Board will be required to include two Directors that are ''Public Directors.'' [74]

[57] *See, e.g.,* Securities Exchange Act Release No 68341 (December 3, 2012), 77 FR 73065, 73067 (December 7, 2012) (''MIAX Exchange Order'') (granting the exchange registration of the Miami International Securities Exchange LLC).

[58] *See, e.g.,* Securities Exchange Act Release No. 53382 (February 27, 2006), 71 FR 11251, 11261 (March 6, 2006) (order approving the New York Stock Exchange, Inc.'s business combination with Archipelago Holdings, Inc.); Nasdaq Exchange Order, *supra* note 52, at 3553; and Securities Exchange Act Release No. 62716 (August 13, 2010), 75 FR 51295, 51298 (August 19, 2010) (approving the application of BATS Y-Exchange, Inc. for registration as a national securities exchange).

[59] 15 U.S.C. 78f(b)(3).

[60] *Id.*

[61] *See, e.g.,* Nasdaq Exchange Order, *supra* note 52; and Securities Exchange Act Release No. 58375 (August 18, 2008), 73 FR 49498 (August 21, 2008) (order granting the exchange registration of BATS Exchange, Inc.).

[62] 15 U.S.C. 78f(b)(3).

[63] *See* Notice, *supra* note 3, at 20516.

[64] *See* Amendment No. 1.

[65] The Exchange states that it held its 2017 Annual Election on June 19, 2017, in accordance with the nomination, petition, and voting processes set forth in the Current Governing Documents. *See id.*

[66] The Commission notes that if the Board of Directors in place at the time the New Governing Documents become effective does not satisfy the requirements in the New Governing Documents, the Exchange would need to comply with the procedures for removing Directors and filling vacancies pursuant to the New Governing Documents. *See, e.g., supra* notes 43, 46, and 51–53 and accompanying text.

[67] *See* Amendment No. 1. As discussed above, the Exchange proposes that, if approved, the New Governing Documents would be made effective no later than by the end of the third quarter of 2017. *See* Amendment No. 1; *see also supra* note 18 and accompanying text.

[68] *See* Notice, *supra* note 3, at 20517. *See also* Amendment No. 1.

[69] *See supra* notes 54–62 and accompanying text (discussing the requirements of Section 6(b)(3) and the Commission's belief that the compositional requirements for the Board of Directors, and the process for electing such Directors under the New Governing Documents, are consistent with those requirements).

[70] *See* Amendment No. 1. *See also* Notice, *supra* note 3, at 20510 and 20513–14 (discussing the Exchange's current process for the nomination and election of Directors, including the Exchange Directors).

''Exchange Rights'' currently means, collectively, PMM Rights, CMM Rights, and EAM Rights, which are the trading and other rights associated with the Exchange's three classes of membership. *See* Rule 100(a)(17); Current LLC Agreement, Article VI; and Current Constitution, Section 13.1(q). *See also* Rules 100(a)(11), 100(a)(14), and 100(a)(36); and Current Constitution, Sections 13.1(g), 13.1(*l*), and 13.1(bb). Under the New Rules, ''Exchange Rights'' will be defined in New Rule 100(a)(19) as the PMM Rights, CMM Rights, and EAM Rights, which will be defined in New Rules 100(a)(39), 100(a)(11), and 100(a)(15), respectively, and as discussed further below. *See infra* Section III.C. (discussing amendments to the Exchange's Rules).

[71] *See* Amendment No. 1; Securities Exchange Act Release No. 42455 (February 24, 2000), 65 FR 11401 (March 2, 2000) (''ISE Exchange Approval'') (granting ISE's application for registration as a national securities exchange); and ISE HoldCo Order, *supra* note 9, at 25265.

[72] *See* Notice, *supra* note 3 at 20517. *See also* Amendment No. 1.

[73] *See* Amendment No. 1.

[74] *See* Current Constitution, Section 3.2(b).

Pursuant to the Exchange's Current Constitution, a ''Public Director'' means a non-industry representative who has no material relationship with a broker or dealer or any affiliate of a broker or dealer or the Exchange or any affiliate of the Exchange. *See* Current Constitution, Sections 3.2(b) and 13.1(cc).

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3. Committees of the Board

Pursuant to the New By-Laws, the Exchange may establish committees composed solely of Directors. Specifically, the Exchange may establish an Executive Committee and a Finance Committee, and shall establish a Regulatory Oversight Committee (''ROC'').[75] The Exchange shall also establish certain committees not composed solely of Directors. Specifically, the Exchange shall establish a Nominating Committee and a Member Nominating Committee, which would be elected on an annual basis by ISE Holdings, as the Sole LLC Member,[76] and a Quality of Markets Committee (''QMC'').[77] The New LLC Agreement will provide that, to the extent provided in the resolution of the Board, any committee that consists solely of one or more Directors shall have and may exercise all the powers and the authority of the Board in the management of the business and affairs of the Exchange.[78] The powers of any such committee would, however, be limited with respect to approving any matters pertaining to the self-regulatory function of the Exchange or relating to the structure of the market the Exchange regulates.[79]

The Exchange proposes that the Executive Committee be an optional committee, to be appointed only if deemed necessary by the Board.[80] Because the Executive Committee will have the powers and authority of the Board in the management of the business and affairs of the Exchange between meetings of the Board, its composition must reflect that of the Board. Accordingly, if established, the number of Non-Industry Directors on the Executive Committee must equal or exceed the number of Industry Directors and the percentages of Public Directors and Member Representative Directors must be at least as great as the corresponding percentages on the Board as a whole.[81]

The Board would retain oversight of the financial operations of the Exchange instead of delegating these functions to a standing committee, but would have the option to appoint a Finance Committee at the Board's discretion.[82] The Finance Committee would advise the Board with respect to the oversight of the financial operations and conditions of the Exchange, including recommendations for the Exchange's annual operating and capital budgets and proposed changes to the rates and fees charged by the Exchange.

The Exchange proposes to eliminate its current Finance and Audit Committee and to have the committee's functions performed by Nasdaq, Inc.'s Audit Committee (''Nasdaq Audit Committee''), which is composed of at least three directors of Nasdaq, Inc., all of whom must satisfy the standards for independence set forth in Section 10A(m) of the Act[83] and Nasdaq's rules.[84] The Exchange notes that the Nasdaq Audit Committee has broad authority to review the financial information that will be provided to shareholders of Nasdaq, Inc. and others; systems of internal controls; and audit, financial reporting, and legal and compliance processes.[85] The Exchange states that, to the extent the current Finance and Audit Committee oversees the Exchange's financial reporting process, its activities are duplicative of the activities of the Nasdaq Audit Committee, which is also charged with providing oversight over financial reporting and independent auditor selection for Nasdaq, Inc. and all of its subsidiaries.[86] The Exchange also notes that the unconsolidated financial statements of the Exchange will still be prepared for each fiscal year.[87]

The Exchange will also have a Regulatory Oversight Committee (''ROC'') under the New Governing Documents, which will have broad authority to oversee the adequacy and effectiveness of the Exchange's regulatory and self-regulatory responsibilities.[88] The ROC will consist of three members, each of whom must be a Public Director and an ''independent director,'' as defined in Nasdaq Rule 5605.[89]

Pursuant to the New By-Laws, the Exchange will also have a Chief Regulatory Officer (''CRO''), as it does currently.[90] The new CRO will have general responsibility for the supervision of the regulatory operations

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The term ''non-industry representative'' means any person who would not be considered an ''industry representative,'' as well as (i) a person affiliated with a broker or dealer that operates solely to assist the securities-related activities of the business of non-member affiliates, or (ii) an employee of an entity that is affiliated with a broker or dealer that does not account for a material portion of the revenues of the consolidated entity, and who is primarily engaged in the business of the non-member entity. *See* Current Constitution, Section 13.1(w).

The term ''industry representative'' means a person who is an officer, director, or employee of a broker or dealer or who has been employed in any such capacity at any time within the prior three (3) years, as well as a person who has a consulting or employment relationship with or has provided professional services to the Exchange and a person who had any such relationship or provided any such services to the Exchange at any time within the prior three (3) years. *See* Current Constitution, Section 13.1(t).

[75] *See* New By-Laws, Article III, Section 5.

The Exchange states that the proposed provisions relating to the standing committees are substantially similar to the provisions in Section 9(g) of the Nasdaq LLC Agreement with respect to standing committees. *See* Amendment No. 1.

[76] *See* New By-Laws, Article III, Section 6(b). *See also supra* note 45 (describing the compositional requirements of these committees).

The Board may also designate additional committees consisting of one or more Directors or other persons. *See* New LLC Agreement, Section 9(g).

[77] *See* New By-Laws, Article III, Section 6(c). *See also infra* note 102 and accompanying text (describing the compositional requirements of the QMC).

[78] *See* New LLC Agreement, Section 9(g)(v).

[79] *See id. See also* Amendment No. 1. The Exchange notes that the proposed limitation is based on substantially similar language in Section 5.2(ii) of MRX's Constitution and is intended to assure the fair administration and governance of the Exchange. The Exchange does not have this limitation in Section 5.2 of its Current Constitution with respect to any Board committees set up by Board resolution, and is therefore proposing to follow the more current MRX standard. *See* Amendment No. 1.

[80] *See* New By-Laws, Article III, Section 5(a).

[81] *See id.*

[82] *See* New By-Laws, Article III, Section 5(b).

[83] *See* U.S.C. 78j–1(m).

[84] *See* Nasdaq, Inc. By-Laws, Section 4.13(g).

The current Finance and Audit Committee must be composed of at least three (3) and not more than five (5) directors, all of whom must be non-industry representatives and must be ''financially literate'' as determined by the Board. *See* Current Constitution, Article V, Section 5.5.

[85] *See* Notice, *supra* note 3, at 20519.

[86] *See id.*

[87] *See id.* The Commission notes that registered national securities exchanges have an ongoing requirement to comply with the requirements of Form 1, which include filing audited financial statements with the Commission on an annual basis. *See* Form 1, General Instructions A.2 and Exhibit I, 17 CFR 249.1; and 17 CFR 240.6a–2(b)(1) (requiring a national securities exchange to file each year, as an amendment to its Form 1, Exhibit I (which requires a Form 1 applicant to file audited financial statements), as of the latest fiscal year of the exchange).

[88] *See* New By-Laws, Article III, Section 5(c). Currently, the Exchange's regulatory oversight activities are performed by the Exchange's Corporate Governance Committee, which will not exist under the new governance structure. *See* Notice, *supra* note 3, at 20520.

The Exchange also states that regulatory oversight functions formerly performed by the Finance and Audit Committee may be assumed by the ROC, and that like the ROCs of the Nasdaq Exchanges, the ISE ROC, because of its broad authority to oversee the adequacy and effectiveness of the Exchange's self-regulatory responsibilities, will be able to maintain oversight over controls in tandem with the Nasdaq Audit Committee's overall oversight responsibilities.

[89] *See* New By-Laws, Article III, Section 5(c).

[90] *See* Notice, *supra* note 3, at 20521 (noting that, although not expressly in its Current Governing Documents, the position of chief regulatory officer has long existed at the Exchange). *See also* New By-Laws, Article IV, Section 7.

In addition to the CRO, pursuant to the New LLC Agreement, the Exchange's officers will include: a Chief Executive Officer, a President, Vice Presidents, a Chief Regulatory Officer, a Secretary, an Assistant Secretary, a Treasurer, and an Assistant Treasurer. *See* New By-Laws, Article IV, Sections 4–11.

of the Exchange and will meet with the ROC in executive session at regularly scheduled meetings of the ROC, and at any time upon request of the CRO or any member of the ROC.[91]

The ROC will assess the Exchange's regulatory performance, assist the Board in reviewing the regulatory plan and the overall effectiveness of the Exchange's regulatory functions, review the Exchange's regulatory budget and inquire into the adequacy of resources available in the budget for regulatory activities, and be informed about the compensation and promotion or termination of the CRO.[92]

The Exchange also proposes that the Internal Audit Department of Nasdaq, Inc. (''Nasdaq Internal Audit Department'') would report to the Board on all Exchange-related internal audit matters and direct such reports to the new ROC.[93] In addition, to ensure that the Board retains authority to direct the Nasdaq Internal Audit Department's activities with respect to the Exchange, the Nasdaq Internal Audit Department's written procedures will stipulate that the ROC may, at any time, direct the Nasdaq Internal Audit Department to conduct an audit of a matter of concern and report the results of the audit both to the ROC and the Nasdaq Audit Committee.[94]

The Exchange also proposes to eliminate its current Compensation Committee and its Corporate Governance Committee.[95] The Compensation Committee is primarily charged with reviewing and approving compensation policies and plans for the Chief Executive Officer and other senior executive officers of the Exchange.[96] Under the new governance structure, the functions of the Compensation Committee will be performed by Nasdaq, Inc.'s management compensation committee or, to the extent that policies, programs, and practices must be established for any Exchange officers or employees who are not also officers or employees of Nasdaq, Inc., the full Board.[97] The Corporate Governance Committee is primarily charged with: (i) Nominating candidates for all vacant or new non-industry representative positions on the Board, (ii) overseeing the Exchange's regulatory activities and program, and (iii) overseeing and evaluating the governance of the Exchange.[98] Under the new governance structure, the functions of the Corporate Governance Committee will be performed by the new Nominating Committee, the new ROC, or, if required, the full Board.[99]

As discussed above, the Nominating Committee and Member Nominating Committee will have responsibility for, among other things, nominating candidates for election to the Board. On an annual basis, the members of these committees will nominate candidates for the succeeding year's respective committees to be elected by ISE Holdings.[100]

Finally, the Quality of Markets Committee (''QMC'') will have the following functions: (i) To provide advice and guidance to the Board on issues relating to the fairness, integrity, efficiency, and competitiveness of the information, order handling, and execution mechanisms of the Exchange from the perspective of investors, both individual and institutional, retail firms, market making firms, and other market participants; and (ii) to advise the Board with respect to national market system plans and linkages between the facilities of the Exchange and other markets.[101] At least 20% of the QMC must be composed of Member Representative members, and the Non-Industry members on the QMC must equal or exceed the sum of Industry members and Member Representative members.[102]

The Commission believes that the Exchange's proposed committees, which are similar to the committees maintained by other exchanges,[103] are designed to help enable the Exchange to carry out its responsibilities under the Act and are consistent with the Act, including Section 6(b)(1), which requires, in part, an exchange to be so organized and have the capacity to carry out the purposes of the Act.[104] The Commission further believes that the Exchange's proposed committees, including their composition and the means by which committee members will be chosen, are consistent with Section 6(b)(3) of the Act because relevant committees provide for the fair representation of members in the administration of the Exchange's affairs.[105]

4. Regulatory Independence

Certain provisions in ISE's Current Governing Documents, and those of its Upstream Owners, are designed to help maintain the independence of the regulatory functions of the Exchange.[106] The New Governing Documents similarly include provisions designed to help maintain the independence of the regulatory functions of ISE,[107] which provisions are substantially similar to those included in the governing documents of other exchanges.[108] Specifically:

- The Exchange Board will be required, when evaluating any proposal, to take into account all factors that the Board deems relevant, including, without limitation, (1) the potential impact on: The integrity, continuity, and stability of the national securities exchange operated by the Exchange and the other operations of the Exchange; the ability to prevent fraudulent and manipulative acts and practices; and

[91] *See* New By-Laws, Article IV, Section 7. The CRO may also serve as the General Counsel of the Exchange. *Id.*

[92] *See* New By-Laws, Article III, Section 5(c).

[93] *See* Notice, *supra* note 3, at 20519 & n.95 (citing the Regulatory Oversight Committee Charter of Nasdaq, Phlx, and BX, *available at http://ir.nasdaq.com/corporate-governance-document.cfm?DocumentID=1097*).

[94] *See id.* at 20519.

[95] *See id.* at 20519–20.

[96] *See id.* at 20519. *See also* Current Constitution, Section 5.6.

[97] *See* Notice, *supra* note 3, at 20519.

[98] *See id.* at 20520. *See also* Current Constitution, Section 5.4.

[99] *See* Notice, *supra* note 3, at 20520.

[100] *See* New By-Laws, Article III, Section 6(c). *See also supra* notes 46–53 and accompanying text. Additional candidates for the Member Nominating Committee may be nominated and elected by Exchange Members pursuant to a petition process. *See supra* notes 49–52 and accompanying text.

The Commission notes that under the New By-Laws, the Member Nominating Committee shall nominate candidates for each Member Representative Director position to be elected by Exchange Members or the Sole LLC Member, and for appointment by the Board for each vacant or new position on any committee that is to be filled with a Member Representative member. *See* New By-Laws, Article III, Section 6.

[101] *See* New By-Laws, Article III, Section 6(c)(i).

[102] *See* New By-Laws, Article III, Section 6(c)(ii). *See also* Notice, *supra* note 3, at 20521; Amendment No. 1.

The Exchange also states that the function of Member Representative members on committees is to provide members a voice in the administration of the Exchange's affairs on certain committees that are responsible for providing advice on any matters pertaining to the Exchange's self-regulatory function or relating to its market structure. *See* Amendment No. 1. In order to ensure that its members have the opportunity to formally provide input on matters that are important to them, the Exchange states that at least 20% of the persons serving on any such committees will be individuals who will have been appointed by the Member Nominating Committee and will be representative of the Exchange's membership. *See id.*

[103] *See, e.g.,* Nasdaq By-Laws Article III, Sections 5–6; BX By-Laws, Article IV, Sections 4.13–14; Phlx By-Laws, Article V, Sections 5–2 to –3.

[104] 15 U.S.C. 78f(b)(1).

[105] *See* 15 U.S.C. 78f(b)(3).

[106] *See, e.g.,* Nasdaq Acquisition Order, *supra* note 4, at 41613–16; Securities Exchange Act Release No. 56955 (December 13, 2007), 72 FR 71979 (December 19, 2007) (SR–ISE–2007–101) (order approving acquisition of ISE Holdings by Eurex Frankfurt); and ISE HoldCo Order, *supra* note 9, at 25263–64.

[107] *See* Notice, *supra* note 3, at 20524. The Commission notes that the Exchange did not propose any amendments to the governing documents of its Upstream Owners.

[108] *See, e.g.,* Nasdaq Exchange Order, *supra* note 52; MIAX Exchange Order, *supra* note 57; Mercury Exchange Approval, *supra* note 28.

investors and the public, and (2) whether such proposal would promote just and equitable principles of trade, foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, or assist in the removal of impediments to or the perfection of the mechanisms for a free and open market and a national market system.[109]

• All books and records of ISE reflecting confidential information pertaining to the self-regulatory function of the Exchange (including but not limited to disciplinary matters, trading data, trading practices, and audit information) shall be retained in confidence by ISE and its officers, directors, employees and agents; shall not be made available to persons other than to those officers, directors, employees, and agents of ISE that have a reasonable need to know; and will not be used for any non-regulatory purpose.[110]

• The Exchange proposes that, as is currently the case, the books and records of ISE must be maintained in the United States [111] and are subject at all times to examination by the Commission pursuant to the federal securities laws and the rules and regulations thereunder.[112]

• Under the New LLC Agreement and New By-Laws, any amendments to those documents will not become effective until filed with, or filed with and approved by, the Commission, as required under Section 19 of the Act and the rules promulgated thereunder.[113]

• Additionally, as is currently the case pursuant to the Current LLC Agreement,[114] Section 15 of the New LLC Agreement would prohibit the Exchange from using Regulatory Funds to pay dividends.[115]

The Commission believes that the provisions discussed in this section, which are designed to help ensure the independence of the Exchange's regulatory function and facilitate the ability of the Exchange to carry out its responsibility and operate in a manner consistent with the Act, are appropriate and consistent with the requirements of the Act, particularly with Section 6(b)(1), which requires, in part, an exchange to be so organized and have the capacity to carry out the purposes of the Act.[116]

The Commission finds that proposed process regarding amendments to the New Governing Documents is consistent with Section 6(b)(1) of the Act, because it reflects the obligation of the Board to ensure compliance with the rule filing requirements under the Act. Additionally, the Commission finds these changes to be consistent with Section 19(b)(1) of the Act and Rule 19b–4 thereunder,[117] which require that a self-regulatory organization file with the Commission all proposed rules, as well as all proposed changes in, additions to, and deletions of its existing rules. These provisions clarify that amendments to the New Governing Documents constitute proposed rule changes within the meaning of Section 19(b)(2) of the Act and Rule 19b–4 thereunder, and are subject to the filing requirements of Section 19 of the Act

[109] *See* New By-Laws, Article III, Section 3. *See also* Amendment No. 1. In Amendment No. 1, the Exchange proposes to clarify in Article III, Section 3 of the New By-Laws the factors to be considered by the Board when evaluating any proposal. *See id.* Further, the Exchange states that Article III, Section 3 of the New By-Laws recognizes the Exchange's status as a self-regulatory organization, and the provisions of Section 3, taken together, are designed to reinforce the notion that the Exchange is not solely a commercial enterprise, but rather a self-regulatory organization registered pursuant to, and subject to the obligations imposed by, the Act. *See* Notice, *supra* note 3, at 20517; Amendment No. 1.

[110] The corresponding provision in ISE's Current LLC Agreement prohibits the use of confidential information for any commercial purpose. *See* Current LLC Agreement, Article IV, Section 4.1(b). The Exchange proposes to modify the standard to prohibit the use of such information for any non-regulatory purpose. *See* Notice, *supra* note 3, at 20512; New LLC Agreement, Section 16. The Exchange states that this change is intended to replicate Section 4.1(b)(iii) of MRX's LLC Agreement, to emphasize the independence of the Exchange's regulatory function from its commercial interests. *See* Amendment No. 1.

Pursuant to Amendment No. 1, the Exchange is not proposing that ISE, and the Board on behalf of ISE, shall not have the right to keep confidential from ISE Holdings, as the Sole LLC Member, any information that the Board would otherwise be permitted to keep confidential from the Sole LLC Member pursuant to Section 18–305(c) of the Delaware Limited Liability Company Act, 6 Del. C. § 18–101. Additionally, the Exchange is not proposing that ISE Holdings, as the Sole LLC Member and the Exchange's authorized representative, shall have an explicit right to examine the Exchange's books, records, and documents during normal business hours. *See* Amendment No. 1. Although such provisions are in the Nasdaq LLC Agreement (*see* Nasdaq LLC Agreement, Section 16), they are not in the Current Governing Documents of ISE.

The Commission believes that the proposed provisions relating to the books and records of the Exchange are designed to maintain the independence of ISE's self-regulatory function, and are consistent with the Act. The Commission notes that these provisions are substantially similar to those the Commission has previously found to be consistent with the Act in the context of the corporate governance structures of other exchanges. *See, e.g.,* MIAX Exchange Order, *supra* note 57; Mercury Exchange Approval, *supra* note 28.

The Commission also notes that the governing documents of ISE's Upstream Owners provide that all books and records of ISE reflecting confidential information pertaining to the self-regulatory function of the Exchange will be subject to confidentiality restrictions. *See* Certificate of Incorporation of ISE Holdings, Article Eleventh; Certificate of Incorporation of U.S. Exchange Holdings, Article Fourteenth; By-Laws of Nasdaq, Inc., Article XII, Section 12.1(b).

[111] *See* New LLC Agreement, Section 16; *see also* Current LLC Agreement, Article IV, Section 4.1.

[112] *See* New LLC Agreement, Section 16. The Commission notes that, as is currently the case, the requirement to keep such information confidential shall not limit the Commission's ability to access and examine such information or limit the ability of officers, directors, employees, or agents of ISE to disclose such information to the Commission. *See id. See also* Current LLC Agreement, Article IV, Section 4.1(b).

The Exchange states that certain provisions in Section 16 of the New LLC Agreement are substantially similar to provisions in Section 16 of the Nasdaq LLC Agreement. *See* Amendment No. 1. The Exchange also states that it is retaining in the New LLC Agreement certain provisions from its Current LLC Agreement that are not in the governing documents of the Nasdaq Exchanges, such as those relating to where the Exchange's books and records must be maintained and who may access the books and records, in particular those books and records that contain confidential information pertaining to the self-regulatory function of the Exchange. *See* Notice, *supra* note 3, at 20512 & n.38.

ISE also states that the Nasdaq Exchanges will separately file proposed rule changes to harmonize the books and records provisions in their respective governing documents with the language in Section 16 of the New LLC Agreement. *See* Notice, *supra* note 3, at 20512 n.38.

[113] *See* New LLC Agreement, Section 27; New By-Laws, Article VIII, Section 1.

The Commission notes that, although the Current Constitution and Current LLC Agreement do not include a similar, explicit requirement regarding the filing of amendments pursuant to Section 19 of the Act, the Current Constitution and Current LLC Agreement, as rules of the Exchange, are nonetheless subject to the requirements of Section 19 of the Act and the rules and regulations thereunder.

Additionally, pursuant to the New By-Laws, either the Sole LLC Member or the vote of a majority of the whole Board may enact amendments to the By-Laws, and that the Board may adopt emergency by-laws.

[114] *See* Current LLC Agreement, Article III, Section 3.3.

[115] Specifically, pursuant to Section 15 of the New LLC Agreement, Regulatory Funds shall not be used non-regulatory purposes, but rather shall be used to fund the legal, regulatory, and surveillance operations of the Exchange, and the Exchange shall not make a distribution to the Sole LLC Member (ISE Holdings) using Regulatory Funds. *See* New LLC Agreement, Section 15.

Consistent with Section 3.3 of the Current LLC Agreement, Schedule A of the New LLC Agreement defines ''Regulatory Funds'' as fees, fines, or penalties derived from the regulatory operations of the Exchange. However, Regulatory Funds do not include revenues derived from listing fees, market data revenues, transaction revenues, or any other aspect of the commercial operations of the Exchange even if a portion of such revenues are used to pay costs associated with the regulatory operations of the Exchange. *See* New LLC Agreement, Schedule A.

ISE states that the Nasdaq Exchanges will separately file proposed rule changes to harmonize the distribution provisions in their respective governing documents with the language in Section 15 of the New LLC Agreement. *See* Amendment No. 1.

[116] 15 U.S.C. 78f(b)(1).

[117] *Id.;* 17 CFR 240.19b–4.

and the rules and regulations thereunder.

The Commission also finds that the prohibition on the use of regulatory fines, fees, or penalties to fund dividends is consistent with Section 6(b)(1) of the Act, because it will further the Exchange's ability to effectively comply with its statutory obligations and is designed to ensure that the regulatory authority of the Exchange is not improperly used.[118] This restriction on the use of regulatory funds is intended to preclude the Exchange from using its authority to raise Regulatory Funds for the purpose of benefiting its shareholders.[119]

C. Related Rule Amendments

While voting rights with respect to Directors will be governed by the New Governing Documents, as is the case today under the Current Governing Documents,[120] the Current Governing Documents also afford certain additional rights to the holders of PMM Rights and CMM Rights (PMM Rights and CMM Rights, each as defined below, and together, ''Market Maker Rights''), namely: [121] (i) the right to vote on any change in, amendment to, or modification of the Core Rights or the definition of ''Core Rights''; [122] and (ii) the right to transfer or lease Market Maker Rights upon approval of the Exchange.[123] The Exchange represents that these rights reflect ISE's original membership structure, where the original Market Maker Rights provided the holders thereof with an equity ownership interest in ISE, as well as trading rights on the Exchange.[124] The Exchange states, however, that today the Market Maker Rights do not confer any equity ownership in the Exchange and are, for all practical purposes, rights to trade on the Exchange.[125] As such, the Exchange believes that the provisions governing the trading privileges of PMMs,[126] CMMs,[127] and EAMs [128] are more appropriately located in its Rules rather than its governance documents. Accordingly, the Exchange proposes to import into its Rules certain provisions relating to Market Maker Rights, as well as Exchange Rights,[129] currently found in the Current Governing Documents.[130] The Exchange states that it is amending its Rules to: (i) Clarify any Rules that cross-reference the Current Governing Documents in the rule text, since those documents are being replaced by the New Governing Documents; or (ii) relocate or memorialize in the Rules certain rights and protections afforded to the Market Marker Rights holders, which today are primarily found in the Current Governing Documents.[131] The Exchange represents that the holders of Exchange Rights will continue to have the same trading privileges they currently hold as PMMs, CMMs, and EAMs under its Rules, and the new Board structure of the Exchange will not change any trading privileges.[132]

Specifically, the Exchange proposed changes to its Rules to, among other things:

- Relocate the concept of CMM Rights from the Current LLC Agreement [133] to New Rule 100(a)(11), which will state that the term ''CMM Rights'' means the transferable rights held by a Competitive Market Maker or a ''non-member owner'' (as that term is defined in Rule 300(a)),[134] and provide in New Rule 100(a)(11) that there are 160 authorized CMM Rights, as is currently set forth in Section 6.1(a) of the Current LLC Agreement.[135]
- Relocate to New Rule 100(a)(12) the definition of ''Competitive Market Maker,'' [136] which is currently only defined in Section 13.1(g) of the Current Constitution.
- Relocate the concept of EAM Rights to New Rule 100(a)(15), which will state that the term ''EAM Rights'' means the non-transferable rights held by an Electronic Access Member.[137]

[118] *See, e.g.,* Securities Exchange Act Release No. 51029 (January 12, 2005), 70 FR 3233, 3241 (January 21, 2005) (SR–ISE–2004–29) (approving an ISE rule interpretation that requires that revenues received from regulatory fees or regulatory penalties be segregated and applied to fund the legal, regulatory, and surveillance operations of the Exchange and not used to pay dividends to the holders of Class A Common Stock).

[119] *See* Notice, *supra* note 3, at 20512.

[120] The Commission notes, however, that in the case of a Contested Election for Member Representative Directors, which is discussed above, instead of electing Directors by class, as is the case under the Current Governing Documents, each PMM, CMM, and EAM Rights holder would cast one vote. *See supra* note 52 and accompanying text.

[121] *See* Notice, *supra* note 3, at 20510.

[122] *See* Current LLC Agreement, Section 6.3(b) and Current Constitution, Section 10.1. ''Core Rights'' represent the voting rights with respect to any increase in the number of authorized Market Maker Rights. *See* Current LLC Agreement, Section 2.2. The number of authorized PMM Rights and CMM Rights are 10 and 160, respectively. *See* Current LLC Agreement, Section 6.1.

[123] *See* Current LLC Agreement, Article VI and Current Constitution, Article XII. According to the Exchange, most of the transfer and lease provisions in the Current Governing Documents are also already in the current Rule 300 Series. *See* Notice, *supra* note 3, at 20510 n.26.

The Commission notes that holders of Exchange Rights also currently have the right to vote on amendments to the Current LLC Agreement or Current By-Laws, if the amendment would alter or change the powers, preferences, or special rights of one or more series of Exchange Rights so as to affect them adversely. *See* Current LLC Agreement, Article VIII, Section 8.1 and Current Constitution, Article X, Section 10.1.

[124] *See* Notice, *supra* note 3, at 20510 & n.27 (citing ISE Exchange Approval, *supra* note 71).

The Exchange notes that all of the initial Market Maker Rights provided the rights holders with an equity ownership interest in ISE as well as trading rights on the Exchange. As such, those rights were transferable or leasable to approved persons or entities (*i.e.,* Exchange members or non-member owners as provided in Rule 300(a)). Additionally, in the past, holders of the Market Maker Rights had the right to vote on corporate actions, such as increasing the number of memberships in a class (akin to the voting rights related to ''Core Rights'' today). The Exchange states that, from the beginning, the holders of EAM Rights had no equity interest in the Exchange and only had rights to trade on the Exchange, and that those rights were not transferable by the holders, and could only be held by Exchange members. The Exchange has since demutualized and reorganized into a holding company structure, all of which resulted in the separation of the equity ownership rights in the Exchange (currently all held by ISE Holdings as the Sole LLC Member) from the trading privileges on the Exchange (currently held by PMMs, CMMs, and EAMs). The holders of PMM Rights and CMM Rights still retain, however, the ability to transfer those rights. *See, e.g.,* Rule 307(a); Current LLC Agreement, Section 6.4; and Current Constitution, Sections 12.1(c), 12.2(c), and 12.3(b). *See also* Notice, *supra* note 3, at 20510 & n.27, 20511.

[125] *See* Notice, *supra* note 3, at 20511.

[126] *See infra* note 140 for the definition of the term, ''PMM.''

[127] *See infra* note 136 for the definition of the term, ''CMM.''

[128] *See infra* note 138 for the definition of the term, ''EAM.''

[129] *See supra* note 70 for the definition of the term ''Exchange Rights.''

[130] The Exchange provides that all the provisions governing the transfer and lease of Market Maker Rights in the Current Governing Documents are substantially set forth in the Rules.

[131] *See* Notice, *supra* note 3, at 20511. The Exchange also proposes certain technical, non-substantive changes, such as changing the term ''Constitution'' to ''By-Laws.''

[132] *See id.*

[133] *See* Current LLC Agreement, Article VI, Section 6.2(b).

[134] CMM Rights are transferable rights. The holders of CMM Rights may lease or sell these rights in accordance with the Exchange's rules and Current Governing Documents. As discussed above, all Exchange Rights (*i.e.,* PMM, CMM, and EAM Rights) convey voting rights and trading privileges on the Exchange. From ISE's inception, however, only the holders of the PMM Rights and CMM Rights could transfer the voting rights and trading privileges associated with such Market Maker Rights, while the voting rights and trading privileges associated with the EAM Rights have never been transferable. *See supra* note 124.

The term ''non-member owners'' is defined as individuals and organizations that are not Members of the Exchange, or that are otherwise Members, but do not seek to exercise trading privileges associated with the Market Maker Rights that they own. *See* Rule 300(a).

The term ''Member'' means an organization that has been approved to exercise trading rights associated with Exchange Rights. *See* current Rule 100(a)(23); New Rule 100(a)(26).

[135] *See* Current LLC Agreement, Article VI, Section 6.1(a).

[136] The term ''Competitive Market Maker'' (referred to herein as ''CMM'') will be defined to mean a Member that is approved to exercise trading privileges associated with CMM Rights. *See* New Rule 100(a)(12).

[137] EAM Rights are non-transferable. Accordingly, the holders of EAM Rights may not lease or sell these rights (unlike PMM and CMM Rights, which

Continued

• Relocate to New Rule 100(a)(16) the definition of ''Electronic Access Member,'' [138] which is currently only defined in Section 13.1(l) of the Current Constitution.

• Relocate the definitions for ''Exchange Transaction,'' ''good standing,'' and ''System'' from the Current Constitution to the Rules,[139] and delete Rule 100(a)(22), defining ''LLC Agreement,'' as that term would no longer be used in the Rules, as amended by the proposed rule change.

• Relocate the concept of PMM Rights from Article VI of the Current LLC Agreement to New Rule 100(a)(39), which will state that the term ''PMM Rights'' means the transferable rights held by a Primary Market Maker or a ''non-member owner'' (as that term is defined in Rule 300(a)), and will state that there are 10 authorized PMM Rights, as is currently set forth in Section 6.1(a) of the Current LLC Agreement.

• Relocate to New Rule 100(a)(40) the definition for ''Primary Market Maker'' [140] from Section 13.1(bb) of the Current Constitution.

The Exchange also proposed to add as new paragraphs (d) and (e) in New Rule 300 certain protections in the Current Governing Documents that relate to the Market Maker Rights. First, new paragraph (d) preserves the concept of Core Rights from the Current Governing Documents, and states that any increase in the number of authorized PMM or CMM Rights must be approved by the affirmative vote of the holders of at least a majority of the then outstanding PMM Rights, voting as a class, and the affirmative vote of the holders of at least a majority of the then outstanding CMM Rights, voting as a class, respectively.[141] Second, new paragraph (e) states that any amendments to the New Governing Documents that would alter or change the powers, preferences, or special rights of one or more series of PMM Rights or CMM Rights must also be approved by the holders of a majority of such PMM or CMM Rights, as applicable. As such, to the extent they relate to the Market Maker Rights holders, paragraph (e) preserves the existing amendment rights from the Current Governing Documents.[142]

The Exchange also proposes to explicitly set forth in its Rules the ownership and voting limitations for the holders of Market Maker Rights.[143] Today, a holder or lessee of Exchange Rights, together with any affiliate, is restricted from owning (or exercising any of the non-trading rights associated with) more than 20% of the PMM Rights or CMM Rights.[144] Consistent with the current limitation, the Exchange proposes to replace the current Supplementary Material .02 to Rule 303 with New Supplementary Material .02, to state that, ''[i]n addition to the trading concentration limits contained in [Rule 303], no holder or lessee of Market Maker Rights, together with any affiliate, may gain ownership or voting rights in excess of 20% of the outstanding PMM Rights or CMM Rights, as applicable.'' [145] The Exchange also states that the New Governing Documents will not have any provisions related to the Market Maker Rights.[146]

The Commission notes that, because the only remaining voting rights associated with PMM Rights and CMM Rights will be the Core Rights and the right to vote on certain amendments to the New Governing Documents, as described above, the voting limitation in Supplementary Material .02 to New Rule 303 will only apply to voting on those matters. Voting on the election of Member Representative members will be governed by Article II of the New By-Laws, as described above.[147]

In the context of a lease of Market Maker Rights, the Exchange proposes to add a requirement in New Rule 308 that the holder of Market Maker Rights must, as is currently required by Section 12.4(b) of the Current Constitution, retain the Core Rights associated with such Market Maker Rights and not transfer such voting rights to the lessee. Section 12.4(b) of the Current Constitution also provides that, under a lease agreement, the lessor may retain the voting rights with respect to the PMM Rights and CMM Rights or may transfer such voting rights, other than the Core Rights, to the lessee. Currently, the voting rights associated with the PMM Rights and CMM Rights that may be retained or transferred are the right to vote in the election of Exchange Directors and the right to vote on amendments to the Current Governing Documents that may adversely affect Market Maker Rights.[148] Pursuant to the New Governing Documents, a holder of Market Maker Rights will continue to have the option of retaining or transferring the right to vote on certain amendments to the New Governing

are transferable). *See* Current Constitution Article XII, Section 12.3. *See also* Notice, *supra* note 3, at 20522 n.111.

The current definition of EAM Rights in Rule 100(a)(14) refers to Article VI of the Current LLC Agreement.

[138] The term ''Electronic Access Member'' (referred to herein as ''EAM'') will be defined to mean a Member that is approved to exercise trading privileges associated with EAM Rights. *See* New Rule 100(a)(16).

[139] ''Exchange Transaction'' would be relocated from Section 13.1(r) of the Current Constitution to New Rule 100(a)(20), ''good standing'' from Section 13.1(s) of the Current Constitution to New Rule 100(a)(23), and ''System'' from Section 13.1(gg) of the Current Constitution to New Rule 100(a)(53).

[140] The term ''Primary Market Maker'' (referred to herein as ''PMM'') will be defined to mean a Member that is approved to exercise trading privileges associated with PMM Rights. *See* New Rule 100(a)(40).

[141] *See* New Rule 300(d). *See also supra* note 122 and accompanying text (discussing the current Core Rights).

[142] *See* New Rule 300(e). *See also* Current LLC Agreement, Section 8.1 and Current Constitution, Section 10.1. As the Exchange notes, the proposed amendment rights for the Market Maker Rights holders in Rule 300(e) are broader than the ones contained in the Current Governing Documents because they will apply for all amendments that affect the powers, preferences, or special rights of one or more series of PMM Rights or CMM Rights, rather than solely to the amendments that adversely affect these Market Maker Rights. *See* Notice, *supra* note 3, at 20523 n.114. *See also supra* note 123. The Commission also notes that any such amendment would also be subject to the voting concentration limitation in the New Supplementary Material .02 to Rule 303, described below (*see infra* notes 143–145 and accompanying text), as well as the requirements of Section 19 of the Act and the rules and regulations thereunder (*see* New LLC Agreement, Section 27; New By-Laws, Article VIII, Section 1).

[143] *See* New Supplementary Material .02 to Rule 303.

[144] *See* Current LLC Agreement, Section 6.5(a). *See also* Amendment No. 1.

Under the Current LLC Agreement, a holder or lessee of Exchange Rights, together with any affiliate, is also restricted from owning (or exercising any of the non-trading rights associated with) more than 20% of the EAM Rights. As discussed above, under the New Governing Documents, a 20% voting limitation will apply to all Exchange Members with respect to participation in Contested Elections, and only holders of PMM and CMM Rights will have a right to vote on certain amendments to the New Governing Documents. *See supra* notes 52 and 142 and accompanying text.

[145] *See* New Supplementary Material .02 to Rule 303. *See also* Amendment No. 1.

The Exchange states that this voting limitation will be calculated by class (*i.e.,* 20% of outstanding PMM Rights or CMM Rights, as applicable) when Market Maker Rights holders are voting on Core Rights or on certain amendments to the New Governing Documents, which is how the voting limitation is applied on the Exchange today. *See* Amendment No. 1. As it relates to voting on the Member Representative Directors only, in the event of a Contested Election, the Exchange states that members will now vote as one class. As such, an Exchange Member (together with any affiliates) may not cast votes representing more than 20% of the votes cast for a candidate. *See id. See also* New By-Laws, Article II, Section 2.

New Supplementary Material .02 to Rule 303 will replace the Current Supplementary Material .02 to Rule 303, which states that in approving any PMM to exercise the trading privileges associated with more than 20% of the outstanding PMM Membership, the Board will not approve any arrangement in which such PMMs would gain ownership or voting rights in excess of those permitted under the Exchange's Current LLC Agreement or Current Constitution.

[146] *See* Amendment No. 1.

[147] *See supra* notes 46–53 and accompanying text.

[148] *See* Amendment No.1. *See also* Current LLC Agreement, Article VI, Section 6.3 and Article VIII, Section 8.1; and Current Constitution, Article X, Section 10.1

Documents. With respect to the right to vote in the case of a Contested Election, the Exchange provides that those voting rights will be transferable under a lease agreement for the holders of Market Maker Rights who are also members of the Exchange.[149] Non-member owners, who are required to lease out their Market Maker Rights pursuant to Rule 300(b) will no longer have voting rights with respect to Directors that represent Exchange Members.[150] The Commission notes that the 20% concentration limitation on voting described above will continue to apply in the case of any transfer of the right to vote in Contested Elections.

The Exchange also proposes to amend New Rule 308 to memorialize the manner in which Market Maker Rights may be subleased. Specifically, the Exchange proposes that a lessee of a Market Maker membership in good standing may sublease such membership to a Member with the permission of the owner.[151] The Exchange states that this is consistent with the Exchange's current practice and will not change the manner in which Market Maker Rights are subleased, but will clarify that such rights may be subleased to an Exchange Member only.[152] Additionally, the Exchange proposes to relocate to the New Rules the requirement from the Current Constitution that a lessor of Market Maker Rights must retain the Core Rights.[153]

The Exchange also proposes to clarify that, for the holders of Market Maker Rights who are also members of the Exchange, the right to vote on Directors representing Exchange Members will continue to be transferable under a lease agreement.[154] Non-member owners, who are required to lease out their Market Maker Rights pursuant to Rule 300(b), will not have voting rights with respect to electing Member Representative Directors.[155] The Exchange states that all voting rights other than Core Rights will remain transferable under a lease agreement, and that New Rule 308(b)(4) requires a lease agreement of Market Maker Rights to include provisions for which party will exercise the voting rights associated with the Market Maker Rights being leased.[156] Accordingly, apart from being relocated from the Current Constitution to the Rules, the Exchange represents that the proposed amendment to New Rule 308 will not change the current transfer rights associated with Market Maker Rights, other than as described above with respect to non-member owners.[157]

The Exchange also proposes to amend New Rule 802(b) to provide that, if a Primary Market Maker fulfills its obligations as a Primary Market Maker under the Rules, the Exchange will not reallocate the options classes to which such Primary Market Maker is appointed, unless otherwise requested by the Primary Market Maker; and would provide that the foregoing will not limit or affect the Exchange's responsibility under Rule 802(d) to reallocate any options classes in the interests of a fair and orderly market.[158] The Exchange states that this proposal is consistent with the manner in which products are allocated to PMMs on the Exchange today.[159] According to the Exchange, today, when ISE lists new options classes, it allocates them to one of its PMMs under Rule 802, and that pursuant to delegated authority by the Board, an Allocation Committee, which consists of employees of the Exchange (''Allocation Committee''), makes allocation decisions according to the guidelines contained in Rule 802.[160] The Exchange also states that the Allocation Committee has not reallocated the products appointed to a PMM since the Exchange's inception for reasons other than as provided in the proposed rule, and as such, the proposed changes are simply to memorialize a longstanding practice on the Exchange.[161]

The Commission believes that the proposed changes to ISE's Rules are consistent with the Act and, in particular Section 6(b)(1) of the Act,[162] which requires among other things that a national securities exchange be so organized and have the capacity to carry out the purposes of the Act. The Commission notes that many of the proposed changes to ISE's Rules are technical in nature, such as renumbering of Rules or conforming terminology to reflect the replacement of the Current Governing Documents with the New Governing Documents. The Commission also notes that, as described above, the Exchange proposes to relocate definitions and provisions related to Market Maker Rights from the Current Governing Documents into the Rules. The Commission believes that the proposed changes to ISE's Rules that would prohibit a holder or lessee of Market Maker Rights, together with any affiliate, from gaining ownership or voting rights in excess of 20% of the outstanding PMM Rights or CMM Rights, as applicable, are consistent with the Act. The Commission has previously stated that a regulatory concern can arise if a member's interest in an exchange becomes so large as to cast doubt on whether the exchange can fairly and objectively exercise its self-regulatory responsibilities with respect to that member.[163] The Commission has stated, for example, that a member that directly or indirectly controls an exchange might be tempted to exercise that controlling influence by directing the exchange to refrain from diligently monitoring and surveilling the member's conduct or diligently enforcing its rules and the federal securities laws with respect to conduct by the member that violates such provisions.[164] The Commission believes that the proposal would not give rise to concerns about the Exchange's ability to effectively carry out its regulatory responsibilities under the Act because the proposed rules change preserves existing ownership and voting limitations.

IV. Accelerated Approval

The Commission finds good cause, pursuant to Section 19(b)(2) of the Act,[165] to approve the proposal, as modified by Amendment No. 1, prior to the 30th day after publication of Amendment No. 1 in the **Federal Register**. In Amendment No. 1, ISE revises the original proposal to make certain changes discussed in greater detail above. Notably, in Amendment No. 1, ISE revises its proposal to (1) make changes to the Exchange's New LLC Agreement and New By-Laws to better align these proposed documents with certain provisions in ISE's existing governing documents and the governing documents of other exchanges, including those concerning limitations on board committee powers, the confidentiality of books and records, the nomination of certain board directors by petition, and the confidentiality of board meetings; (2) revise the proposed

[149] *See* Amendment No. 1.

[150] *See id.*

[151] *See id.*

[152] *Id. See also* New Rule 308.

[153] *See* Notice, *supra* note 3, at 20523. *See also* Amendment No. 1; and New Rule 308.

[154] *See* Amendment No. 1.

[155] As described above, under the New By-Laws, in the case of a Contested Election, each Exchange Member shall have the right to cast one vote for each Member Representative Director. *See* New By-Laws, Article II, Section 2. *See also supra* note 52; Amendment No. 1.

[156] *See* Amendment No. 1.

[157] *See id.*

[158] *See* New Rule 802(b)(2).

[159] *See* Notice, *supra* note 3, at 20523.

[160] *See id.*

[161] *See id.*

[162] 15 U.S.C. 78f(b)(1).

[163] *See, e.g.,* ISE HoldCo Order, *supra* note 9, at 25262 n.38 and accompanying text.

[164] *See, e.g., id.* at 25262.

[165] 15 U.S.C. 78s(b)(2).

amendments to ISE's rules regarding ownership, voting, and transfer restrictions relating to certain market maker rights on the Exchange; (3) revise the related discussion of the purpose of the proposed changes; (4) add clarification to the description of the proposal regarding the operation of certain provisions; and (5) make certain technical corrections. The Commission believes that Amendment No. 1 does not raise any novel regulatory issues and instead better aligns ISE's proposed New Governing Documents with certain provisions in its Current Governing Documents and the governing documents of other exchanges that were previously approved by the Commission.[166] As discussed more fully above, certain provisions of ISE's New Governing Documents, as modified by Amendment No. 1, are designed to facilitate the ability of ISE to maintain the independence of its self-regulatory function, enable it to operate in a manner that complies with the federal securities laws, and facilitate the ability of ISE and the Commission to fulfill their regulatory and oversight obligations under the Act.[167] The Commission further believes that Amendment No. 1 provides additional clarity in the rule text and the description of the proposal, which is consistent with ISE's original proposal and supports ISE's analysis of how its proposal is consistent with the Act, thus facilitating the Commission's ability to make the findings set forth above to approve the proposal. Accordingly, the Commission finds that good cause exists to approve the proposal, as modified by Amendment No. 1, on an accelerated basis.

V. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning Amendment No. 1, including whether Amendment No. 1 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–ISE–2017–32 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–ISE–2017–32. 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–ISE–2017–32 and should be submitted on or before August 25, 2017.

VI. Conclusion

It is therefore ordered, pursuant to Section 19(b)(2) of the Act,[168] that theproposed rule change (SR–ISE–2017–32), as modified by Amendment No. 1, be, and hereby is, approved on an accelerated basis.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[169]

Eduardo A. Aleman,

Assistant Secretary.

[FR Doc. 2017–16398 Filed 8–3–17; 8:45 am]

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[166] *See, e.g.,* Securities Exchange Act Release Nos. 70050 (July 26, 2013), 78 FR 46622 (August 1, 2013) (granting GEMX's (f/k/a Topaz Exchange, LLC) application for registration as a national securities exchange); and Mercury Exchange Approval, *supra* note 28.

[167] *See supra* Section III.B.4 (discussing, for example, certain provisions in ISE's New Governing Documents that are designed to help maintain the independence of the regulatory functions of the Exchange).

[168] 15 U.S.C. 78s(b)(2).

[169] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–81269; File No. SR–NYSENAT–2017–03]

Self-Regulatory Organizations; NYSE National, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change Amending Rule 11.26 To Modify the Date of Appendix B Web site Data Publication Pursuant to the Regulation NMS Plan To Implement a Tick Size Pilot Program

July 31, 2017.

Pursuant to Section 19(b)(1) [1] of the Securities Exchange Act of 1934 (the ''Act'') [2] and Rule 19b–4 thereunder,[3] notice is hereby given that on July 18, 2017, NYSE National, Inc. (the ''Exchange'' or ''NYSE NAT'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend Rule 11.26 to modify the date of Appendix B Web site data publication pursuant to the Regulation NMS Plan to Implement a Tick Size Pilot Program (''Plan''). The proposed rule change is available on the Exchange's Web site at *www.nyse.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

[1] 15 U.S.C. 78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

Rule 11.26(b) (Compliance with Data Collection Requirements) [4] implements the data collection and Web site publication requirements of the Plan.[5] Interpretations and Policies .08 to Rule 11.26 provides, among other things, that the requirement that the Exchange or their [sic] DEA make certain data publicly available on the Exchange's or DEA's Web site pursuant to Appendix B and C to the Plan shall commence at the beginning of the Pilot Period, [6] and that the Exchange or their [sic] DEA shall make data for the Pre-Pilot Period publicly available on the Exchange's or DEA's Web site pursuant to Appendix B and C of the Plan by February 28, 2017.[7]

The Exchange is proposing to amend Interpretations and Policies .08 to Rule 11.26 to delay the date by which Pre-Pilot and Pilot Appendix B data is to be made publicly available on the Exchange's or DEA's Web site from February 28, 2017, until August 31, 2017.[8] Appendix C data for the Pre-Pilot Period through the month of January 2017 was published on the DEA's Web site on February 28, 2017, and, thereafter, on the original 30-day schedule.

The Exchange is also proposing to delete the words ''and make certain data publicly available on the Exchange's or DEA's Web site'' in the second sentence to Interpretations and Policies .08 to Rule 11.26 as it is duplicate of the requirement in third sentence.

Pursuant to this proposed amendment, Appendix B data publication would be delayed until August 31, 2017, with the Exchange publishing the required Appendix B data for the Pre-Pilot Period through April 30, 2017, by August 31, 2017. Thereafter, Appendix B data for a particular month would be published within 120 calendar days following such month end. Thus, for example, Appendix B data for May 2017 would be made available on the Exchange's or DEA's Web site by September 28, 2017, and data for June 2017 would be made available on the Exchange's or DEA's Web site by October 28, 2017. This proposed rule change would align the Exchange's rules with those of the other Participants and is consistent with the Commission's Exemptive Relief I and Exemptive Relief II.[9]

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act,[10] in general, and furthers the objectives of Section 6(b)(5) of the Act,[11] in particular, in that it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest.

The Plan is designed to allow the Commission, market participants, and the public to study and assess the impact of increment conventions on the liquidity and trading of the common stock of small-capitalization companies. The Exchange believes that this proposal is consistent with the Act because it is in furtherance of the objectives of Section VII(A) of the Plan in that it is designed to provide the Exchange with additional time to assess a means of addressing the confidentiality concerns raised in connection with the publication of Appendix B data and to comply with the Plan's requirements that the data made publicly available will not identify the trading center that generated the data.

The Exchange ceased operations on February 1, 2017 and erroneously understood that it was not thereafter required to modify its rules to reflect extensions of the deadlines to publish data on its Web site. The purpose of this filing is to correct that error and would align the Exchange's rules with the rules of the other Participants and is consistent with the Commission's Exemptive Relief I and Exemptive Relief II.

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. To the contrary, the proposed rule change will result in the Exchange's rules being consistent with those of other national securities exchanges and all of the other Participants under the Plan.[12] The Exchange believes that the proposed amendment is consistent with the goal of removing impediments to a free and open market because it would harmonize the Exchange's rules with rules of other exchanges, further promote fair competition in trading among exchanges, and help implement the provisions of the Plan, as it is designed to assist the Participants in meeting their regulatory obligations pursuant to the Plan.

[4] *See* Securities Exchange Act Release No. 77483 (March 31, 2016), 81 FR 20040 (April 6, 2016) (Immediate Effectiveness of Proposed Rule Change To Adopt Exchange Rule 11.26 To Implement the Regulation NMS Plan To Implement a Tick Size Pilot Program) (SR–NSX–2016–01); *see also* Securities Exchange Act Release No. 78960 (September 28, 2016), 81 FR 68476 (October 4, 2016) (Immediate Effectiveness of Proposed Rule Change to Amend Rule 11.26 to Modify Certain Data Collection Requirements of the Regulation NMS Plan to Implement a Tick Size Pilot Program) (SR–NSX–2016–12); *see also* Letter from John C. Roeser, Associate Director, Division of Trading and Markets, Commission, to James Buckley, Chief Regulatory Officer, National Stock Exchange, Inc., dated April 4, 2016.

[5] The Participants filed the Plan to comply with an order issued by the Commission on June 24, 2014. *See* Letter from Brendon J. Weiss, Vice President, Intercontinental Exchange, Inc., to Secretary, Commission, dated August 25, 2014 (''SRO Tick Size Plan Proposal''). *See* Securities Exchange Act Release No. 72460 (June 24, 2014), 79 FR 36840 (June 30, 2014); *see also* Securities Exchange Act Release No. 74892 (May 6, 2015), 80 FR 27513 (May 13, 2015).

[6] Unless otherwise defined herein, capitalized terms have the meaning ascribed to them in the Plan.

[7] On November 30, 2016, the SEC granted exemptive relief to the Participants to, among other things, delay the publication of Web site data pursuant to Appendices B and C to the Plan until February 28, 2017, and to delay the ongoing Web site publication by ninety days such that data would be published within 120 calendar days following the end of the month. *See* Letter from David S. Shillman, Associate Director, Division of Trading and Markets, Commission, to Marcia E. Asquith, Senior Vice President and Corporate Secretary, Financial Industry Regulatory Authority, Inc. (''FINRA''), dated November 30, 2016; *see also* Securities Exchange Act Release No. 79806 (January 17, 2017), 82 FR 8249 (January 24, 2017 and corrected on February 3, 2017) (Notice of Filing and Immediate Effectiveness of File No. SR–NSX–2017–01).

[8] On February 28, 2017, the SEC granted exemptive relief to the Participants to delay the publication of Web site data pursuant to Appendix B to the Plan until April 28, 2017 (''Exemptive Relief I''). *See* Letter from David S. Shillman, Associate Director, Division of Trading and Markets, Commission, to Mr. Robert L.D. Colby, Executive Vice President and Chief Legal Officer, FINRA, dated February 28, 2017.

On April 28, 2017, the SEC granted exemptive relief to the Participants to further delay the publication of Web site data pursuant to Appendix B to the Plan from April 28, 2017 until August 31, 2017 (''Exemptive Relief II''). *See* Letter from David S. Shillman, Associate Director, Division of Trading and Markets, Commission, to Ms. Jennifer Piorko Mitchell, Vice President and Deputy Corporate Secretary, FINRA, dated April 28, 2017.

[9] *Id.*

[10] 15 U.S.C. 78f(b).

[11] 15 U.S.C. 78f(b)(5).

[12] *See, e.g.,* Bats BZX Exchange, Inc. Rule 11.27; Bats BYX Exchange, Inc. Rule 11.27; Bats EDGA Exchange, Inc. Rule 11.21; Bats EDGX Exchange, Inc. Rule 11.22; Chicago Stock Exchange, Inc. Article 20, Rule 13; Investors Exchange LLC Rule 11340; NASDAQ BX, Inc. Rule 4770; Nasdaq Stock Market LLC Rule 4770; NASDAQ PHLX LLC Rule 3317; FINRA Rule 6191; New York Stock Exchange LLC Rule 67; NYSE MKT LLC Rule 67-Equities; and NYSE Arca, Inc. Rule 7.46.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The Exchange has designated this proposed rule change as non-controversial under Section 19(b)(3)(A)(iii) of the Act [13] and Rule 19b–4(f)(6) thereunder.[14] Because the proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative prior to 30 days from the date on which it was filed, or such shorter time as the Commission may designate, if consistent with the protection of investors and the public interest, the proposed rule change has become effective pursuant to Section 19(b)(3)(A) of the Act and Rule 19b–4(f)(6) thereunder.

A proposed rule change filed under Rule 19b–4(f)(6) [15] normally does not become operative prior to 30 days after the date of the filing. However, pursuant to Rule 19b–4(f)(6)(iii),[16] the Commission may designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange has asked the Commission to waive the 30-day operative delay so that the proposal may become operative immediately upon filing. The Exchange believes that waiving the operative delay would be consistent with the protection of investors and the public interest because the proposed rule change would immediately align the Exchange's rules with those of the other Participants.[17] The Commission believes that synchronizing the timing for publication of Appendix B data for all Participants should enhance the consistency and usefulness of the data.[18] Therefore, the Commission hereby waives the operative delay and designates the proposed rule change operative upon filing.[19]

[13] 15 U.S.C. 78s(b)(3)(A)(iii).

[14] 17 CFR 240.19b–4(f)(6).

[15] 17 CFR 240.19b–4(f)(6).

[16] 17 CFR 240.19b–4(f)(6)(iii).

[17] *See supra* note 12.

[18] *See* Exemptive Relief II, *supra* note 8.

[19] 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).

At any time within 60 days of the filing of such proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings under Section 19(b)(2)(B) [20] of the Act to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–NYSENAT–2017–03 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–NYSENAT–2017–03. 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–NYSENAT–2017–03 and should be submitted on or before August 25, 2017.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[21]

Eduardo A. Aleman,

Assistant Secretary.

[FR Doc. 2017–16404 Filed 8–3–17; 8:45 am]

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[20] 15 U.S.C. 78s(b)(2)(B).

[21] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–81267; File No. SR–NYSEArca–2017–36]

Self-Regulatory Organizations; NYSE Arca, Inc.; Order Instituting Proceedings To Determine Whether To Approve or Disapprove a Proposed Rule Change To Adopt NYSE Arca Equities Rule 8.900 To Permit Listing and Trading of Managed Portfolio Shares and To List and Trade Shares of the Royce Pennsylvania ETF; Royce Premier ETF; and Royce Total Return ETF Under Proposed NYSE Arca Equities Rule 8.900

July 31, 2017.

On April 14, 2017, NYSE Arca, Inc. (''Exchange'' or ''NYSE Arca'') filed with the Securities and Exchange Commission (''Commission''), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'') [1] and Rule 19b–4 thereunder,[2] a proposed rule change to: (1) Adopt NYSE Arca Equities Rule 8.900 (Managed Portfolio Shares); and (2) list and trade shares (''Shares'') of the Royce Pennsylvania ETF, Royce Premier ETF, and Royce Total Return ETF under proposed NYSE Arca Equities Rule 8.900. The proposed rule change was published for comment in the **Federal Register** on May 4, 2017.[3] On June 15, 2017, pursuant to Section 19(b)(2) of the Act,[4] the Commission designated a longer period within which to approve the proposed rule change, disapprove the proposed rule change, or institute proceedings to determine whether to disapprove the proposed

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 80553 (April 28, 2017), 82 FR 20932 (''Notice'').

[4] 15 U.S.C. 78s(b)(2).

rule change.[5] The Commission has received four comments on the proposed rule change.[6] This order institutes proceedings under Section 19(b)(2)(B) of the Act[7] to determine whether to approve or disapprove the proposed rule change.

Summary of the Exchange's Description of the Proposed Rule Change[8]

The Exchange proposes to adopt new NYSE Arca Equities Rule 8.900, which would govern the listing and trading of ''Managed Portfolio Shares.''[9] The Exchange also proposes to list and trade the Shares of the Royce Pennsylvania ETF, Royce Premier ETF, and Royce Total Return ETF under proposed NYSE Arca Equities Rule 8.900 (each a ''Fund,'' and collectively the ''Funds'').

A. Description of the Funds

The portfolio for each Fund will consist of long and/or short positions in U.S.-listed securities and shares issued by other U.S.-listed exchange-traded funds (''ETFs'').[10] All exchange-listed equity securities in which the Funds will invest will be listed and traded on U.S. national securities exchanges.

1. Royce Pennsylvania ETF

The Royce Pennsylvania ETF will invest primarily in U.S.-listed equity securities of small-cap companies with market capitalizations up to $3 billion that Royce & Associates, LP (''Royce''), the Fund's investment sub-adviser, believes are trading below the sub-adviser's estimate of their current worth. The Fund may invest in other investment companies that invest in equity securities. The Fund may sell securities to, among other things, secure gains, limit losses, re-deploy assets into what Royce deems to be more promising opportunities, and/or manage cash levels in the Fund's portfolio.

2. Royce Premier ETF

The Royce Premier ETF will invest in a limited number of U.S.-listed equity securities of primarily small-cap companies with market capitalizations from $1 billion to $3 billion at the time of investment. The Fund may invest in other investment companies that invest in equity securities. The Fund may sell securities to, among other things, secure gains, limit losses, re-deploy assets into what Royce deems to be more promising opportunities, and/or manage cash levels in the Fund's portfolio.

3. Royce Total Return ETF

The Royce Total Return ETF will invest primarily in dividend-paying U.S.-listed securities of small-cap companies with market capitalizations up to $3 billion that the sub-adviser believes are trading below its estimate of their current worth. The Fund may invest in other investment companies that invest in equity securities. The Fund may sell securities to, among other things, secure gains, limit losses, re-deploy assets into what Royce deems to be more promising opportunities, and/or manage cash levels in the Fund's portfolio.

4. Other Investments

According to the Exchange, while each Fund, under normal market conditions, will invest primarily in U.S.-listed securities, as described above, each Fund may invest its remaining assets in other securities and financial instruments as follows: (i) Repurchase agreements;[11] (ii) warrants, rights, and options (limited to 5% of total assets); (iii) cash or cash equivalents;[12] and (iv) other investment companies (including money market funds).

5. Investment Restrictions

Each Fund may invest up to an aggregate amount of 15% of its net assets in illiquid assets (calculated at the time of investment),[13] consistent with Commission guidance. Each Fund will monitor its portfolio liquidity on an ongoing basis to determine whether, in light of current circumstances, an adequate level of liquidity is being maintained, and will consider taking appropriate steps in order to maintain adequate liquidity if, through a change in values, net assets, or other circumstances, more than 15% of a Fund's net assets are invested in illiquid assets. Illiquid assets include securities subject to contractual or other restrictions on resale and other instruments that lack readily available markets as determined in accordance with Commission staff guidance.

The Funds will not invest in futures, forwards, or swaps. Further, each Fund's investments will be consistent with its investment objective and will not be used to enhance leverage. While a Fund may invest in inverse ETFs, a Fund will not invest in leveraged (*e.g.,* 2X, –2X, 3X or –3X) ETFs. Finally, the Funds will not invest in non-U.S.-listed securities.

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[5] *See* Securities Exchange Act Release No. 80935, 82 FR 28152 (June 20, 2017). The Commission designated August 2, 2017, as the date by which the Commission shall approve or disapprove, or institute proceedings to determine whether to disapprove, the proposed rule change.

[6] *See* Letter from Gary L. Gastineau, President, ETF Consultants.com, Inc., to Brent J. Fields, Secretary, Commission, dated May 24, 2017 (''Gastineau Letter''); Letter from Todd J. Broms, Chief Executive Officer, Broms & Company LLC, to Brent J. Fields, Secretary, Commission, dated May 25, 2017 (''Broms Letter''); Letter from James J. Angel, Associate Professor of Finance, Georgetown University, McDonough School of Business, to the Commission, dated May 25, 2017 (''Angel Letter''); and Terence W. Norman, Founder, Blue Tractor Group, LLC, to Brent J. Fields, Secretary, Commission, dated July 18, 2017 (''Norman Letter''). The comment letters are available on the Commission's Web site at: *https://www.sec.gov/comments/sr-nysearca-2017-36/nysearca201736.htm.*

[7] 15 U.S.C. 78s(b)(2)(B).

[8] For a complete description of the Exchange's proposal, including a description of the Precidian ETFs Trust (''Trust''), *see* the Notice *supra* note 3.

[9] Proposed NYSE Arca Equities Rule 8.900(c)(1) defines the term ''Managed Portfolio Share'' as a security that (a) is issued by a registered investment company organized as an open-end management investment company (''Investment Company'') or similar entity, that invests in a portfolio of securities selected by the Investment Company's investment adviser consistent with the Investment Company's investment objectives and policies; and (b) when aggregated in a number of shares equal to a Redemption Unit (as defined in proposed NYSE Arca Equities Rule 8.900(c)(3)) or multiples thereof, may be redeemed at the request of an authorized participant (as defined in the Investment Company's Form N–1A filed with the Commission), which authorized participant will be paid through a confidential account (''Confidential Account'') established for its benefit a portfolio of securities and/or cash with a value equal to the next determined net asset value (''NAV'').

[10] The Exchange represents that, for purposes of the filing, ETFs include Investment Company Units (as described in NYSE Arca Equities Rule 5.2(j)(3)); Portfolio Depository Receipts (as described in NYSE Arca Equities Rule 8.100); and Managed Fund Shares (as described in NYSE Arca Equities Rule 8.600). The ETFs in which a Fund will invest all will be listed and traded on national securities exchanges. While the Funds may invest in inverse ETFs, the Funds will not invest in leveraged (*e.g.,* 2X, -2X, 3X, or -3X) ETFs.

[11] The Exchange states that it will be the policy of the Trust to enter into repurchase agreements only with recognized securities dealers, banks, and the Fixed Income Clearing Corporation.

[12] The Exchange states that for purposes of the filing, cash equivalents include short-term instruments (instruments with maturities of less than 3 months) of the following types: (i) U.S. Government securities, including bills, notes, and bonds differing as to maturity and rates of interest, which are either issued or guaranteed by the U.S. Treasury or by U.S. Government agencies or instrumentalities; (ii) certificates of deposit issued against funds deposited in a bank or savings and loan association; (iii) bankers' acceptances, which are short-term credit instruments used to finance commercial transactions; (iv) repurchase agreements and reverse repurchase agreements; (v) bank time deposits, which are monies kept on deposit with banks or savings and loan associations for a stated period of time at a fixed rate of interest; (vi) commercial paper, which are short-term unsecured promissory notes; and (vii) money market funds.

[13] In reaching liquidity decisions, the Adviser may consider the following factors: The frequency of trades and quotes for the security; the number of dealers wishing to purchase or sell the security and the number of other potential purchasers; dealer undertakings to make a market in the security; and the nature of the security and the nature of the marketplace in which it trades (*e.g.,* the time needed to dispose of the security, the method of soliciting offers and the mechanics of transfer).

B. Key Features of Managed Portfolio Shares

While Investment Companies issuing Managed Portfolio Shares would be actively-managed, and in that respect would be similar to those issuing Managed Fund Shares,[14] Managed Portfolio Shares would differ from Managed Fund Shares in the following respects.

• First, issues of Managed Fund Shares are required to disseminate their ''Disclosed Portfolio'' at least once daily.[15] By contrast, the portfolio for an issue of Managed Portfolio Shares would be disclosed only quarterly.

• Second, in connection with the redemption of shares in ''Redemption Unit'' size, the delivery of any portfolio securities in kind would be effected through a Confidential Account for the benefit of the redeeming authorized participant without disclosing the identity of the securities to the authorized participant.

• Third, for each series of Managed Portfolio Shares, a Verified Intraday Indicative Value (''VIIV'') would be disseminated by one or more major market-data vendors every second during the Exchange's Core Trading Session (normally, 9:30 a.m. to 4:00 p.m., Eastern Time (''E.T.'')).[16] The Exchange states that dissemination of the VIIV will allow investors to determine the estimated intra-day value of the underlying portfolio of a series of Managed Portfolio Shares and will provide a close estimate of that value throughout the trading day.[17]

C. Arbitrage of Managed Portfolio Shares

The Exchange asserts that market makers will be able to make efficient and liquid markets priced near the VIIV, as long as a VIIV is disseminated every second, market makers have knowledge of a Fund's means of achieving its investment objective, and market makers are permitted to engage in ''bona fide arbitrage,'' as described below. According to the Exchange, market makers would employ bona fide arbitrage in addition to risk-management techniques such as ''statistical arbitrage,'' [18] which the Exchange states is currently used throughout the financial services industry to make efficient markets in ETFs.

Moreover, according to the Exchange, if an authorized participant believes that Shares of a Fund are trading at a price that is higher than the value of the underlying portfolio—for example, if the market price for the Shares is higher than the VIIV—then the authorized participant may sell Shares of the Fund short and instruct its ''Trusted Agent'' [19] to buy portfolio securities for its Confidential Account. When the market price of the Shares falls in line with the value of the portfolio, the authorized participant can then close out its positions in both the Shares and the portfolio securities. According to the Exchange, the authorized participant's purchase of the portfolio securities into its Confidential Account, combined with the sale of Shares, may create downward pressure on the price of Shares and/or upward pressure on the price of the portfolio securities, bringing the market price of Shares and the value of a Fund's portfolio securities closer together.

Similarly, according to the Exchange, an authorized participant could buy Shares and instruct the Trusted Agent to sell the underlying portfolio securities from its Confidential Account in an attempt to profit when a Fund's Shares are trading at a discount to its portfolio. According to the Exchange, the authorized participant's purchase of a Fund's Shares in the secondary market, combined with the sale of the portfolio securities from its Confidential Account, may create upward pressure on the price of Shares and/or downward pressure on the price of portfolio securities, driving the market price of Shares and the value of a Fund's portfolio securities closer together. The Exchange states that, according to Precidian Funds LLC (''Adviser''), the investment adviser to the Trust, this process is identical to how many authorized participants currently arbitrage existing traditional ETFs, except for the use of the Confidential Account.

According to the Exchange, a market participant that is not an authorized participant would also be able to establish a Confidential Account and could engage in arbitrage activity without using the creation or redemption processes described above. If such a market participant believes that a Fund is overvalued relative to its underlying assets, the Exchange states, that market participant could sell Shares short and instruct its Trusted Agent to buy portfolio securities in its Confidential Account and then wait for the trading prices to move toward parity and close out the positions in both the Shares and the portfolio securities to realize a profit from the relative movement of their trading prices. Similarly, according to the Exchange, this market participant could buy Shares and instruct the Trusted Agent to sell the underlying portfolio securities in an attempt to profit when a Fund's Shares are trading at a discount to a Fund's underlying or reference assets.

D. The Creation and Redemption Procedures

The Exchange states that, generally, Shares will be purchased and redeemed on an in-kind basis, so that, except where the purchase or redemption will include cash under the circumstances described in the applicable Fund's registration statement, purchasers will be required to purchase ''Creation Units'' by making an in-kind deposit of

[14] Managed Fund Shares are shares of actively-managed Investment Companies listed and traded under NYSE Arca Equities Rule 8.600.

[15] NYSE Arca Equities Rule 8.600(c)(2) defines the term ''Disclosed Portfolio'' as the identities and quantities of the securities and other assets held by the Investment Company that will form the basis for the Investment Company's calculation of NAV at the end of the business day. NYSE Arca Equities Rule 8.600(d)(2)(B)(i) requires that, for Managed Fund Shares, the Disclosed Portfolio will be disseminated at least once daily and will be made available to all market participants at the same time.

[16] Proposed NYSE Arca Equities Rule 8.900(c)(2) defines the VIIV as the estimated indicative value of a Managed Portfolio Share based on all of the issuer's holdings as of the close of business on the prior business day, priced and disseminated in one second intervals, and subject to validation by a pricing verification agent of the Investment Company that is responsible for comparing multiple independent pricing sources to establish the accuracy of the VIIV. The specific methodology for calculating the VIIV will be disclosed on each Fund's Web site.

[17] According to the Exchange, the VIIV should not be viewed as a ''real-time'' update of the NAV per Share of each Fund, because the VIIV may not be calculated in the same manner as the NAV, which will be computed once a day, generally at the end of the business day.

[18] According to the Exchange, statistical arbitrage enables a trader to construct an accurate proxy for another instrument, allowing the trader to hedge the other instrument or buy or sell the instrument when it is cheap or expensive in relation to the proxy. Statistical analysis permits traders to discover correlations based purely on trading data without regard to other fundamental drivers. These correlations are a function of differentials, over time, between one instrument or group of instruments and one or more other instruments. Once the nature of these price deviations has been quantified, a universe of securities is searched in an effort to, in the case of a hedging strategy, minimize the differential. Once a suitable hedging proxy has been identified, a trader can minimize portfolio risk by executing the hedging basket. The trader then can monitor the performance of this hedge throughout the trade period making correction where warranted.

[19] Proposed Commentary .04 to NYSE Arca Equities Rule 8.900 requires that authorized participants and non-authorized participant market makers redeeming Managed Portfolio Shares sign an agreement with an agent (''Trusted Agent'') to establish a Confidential Account, for the benefit of such authorized participant or non-authorized participant market maker, that will receive all consideration from the issuer in a redemption. A Trusted Agent may not disclose the consideration received in a redemption except as required by law or as provided in the Investment Company's Form N–1A, as applicable.

specified instruments (''Deposit Instruments''), and shareholders redeeming their Shares will receive an in-kind transfer of specified instruments (''Redemption Instruments''). On any given business day, the names and quantities of the instruments that constitute the Deposit Instruments and the names and quantities of the instruments that constitute the Redemption Instruments will be identical, and these instruments may be referred to, in the case of either a purchase or a redemption, as the ''Creation Basket.''

In the case of a redemption, a Fund's custodian (''Custodian'') will typically deliver securities to the Confidential Account on a *pro rata* basis with a value approximately equal to the value of the Shares tendered for redemption at the order cut-off time established by the Fund. The Custodian will make delivery of the securities by appropriate entries on its books and records transferring ownership of the securities to the authorized participant's Confidential Account, subject to delivery of the Shares redeemed. The Trusted Agent of the Confidential Account will in turn liquidate, hedge, or otherwise manage the securities based on instructions from the authorized participant.[20]

If the Trusted Agent is instructed to sell all securities received at the close on the redemption date, the Trusted Agent will pay the liquidation proceeds net of expenses, plus or minus any cash balancing amount, to the authorized participant through DTC.[21] The redemption securities that the Confidential Account receives are expected to mirror the portfolio holdings of a Fund *pro rata.*

E. Availability of Information

Each Fund will be required to file with the Commission its complete portfolio schedules for the second and fourth fiscal quarters on Form N–CSR under the 1940 Act, and to file its complete portfolio schedules for the first and third fiscal quarters on Form N–Q under the 1940 Act, within 60 days of the end of the quarter. Form N–Q requires funds to file the same schedules of investments that are required in annual and semi-annual reports to shareholders. The Trust's SAI and each Fund's shareholder reports will be available free upon request from the Trust. These documents and forms may be viewed on-screen or downloaded from the Commission's Web site at *www.sec.gov.*

In addition, the VIIV will be widely disseminated by one or more major market-data vendors at least every second during the Exchange's Core Trading Session through the facilities of the Consolidated Tape Association. According to the Exchange, the VIIV will include all accrued income and expenses of a Fund and will assure that any extraordinary expenses, booked during the day, that would be taken into account in calculating a Fund's NAV for that day are also taken into account in calculating the VIIV.

For purposes of the VIIV, securities held by a Fund will be valued throughout the day based on the mid-point between the disseminated current national best bid and offer. According to the Exchange, by utilizing the mid-point pricing for purposes of VIIV calculation, stale prices are eliminated and more accurate representation of the real-time value of the underlying securities is provided to the market. Specifically, according to the Exchange, quotations based on the mid-point of bid/ask spreads more accurately reflect current market sentiment by providing real time information on where market participants are willing to buy or sell securities at that point in time. The Exchange also believes that the use of quotations will dampen the impact of any momentary spikes in the price of a portfolio security.

According to the Exchange, each Fund will utilize two independent pricing sources to provide pricing information. Each Fund will also utilize a ''Pricing Verification Agent'' and establish a computer-based protocol that will permit the Pricing Verification Agent to continuously compare the two data streams from the independent pricing sources on a real time basis.[22] A single VIIV will be disseminated publicly for each Fund; however, the Pricing Verification Agent will continuously compare the public VIIV against a non-public alternative intra-day indicative value to which the Pricing Verification Agent has access. If it becomes apparent that there is a material discrepancy between the two data streams, according to the proposal, the Exchange will be notified and have the ability to halt trading in a Fund until the discrepancy is resolved.[23] Each Fund's board of directors will review the procedures used to calculate the VIIV and maintain its accuracy as appropriate, but not less than annually. The specific methodology for calculating the VIIV will be disclosed on each Fund's Web site.

F. Surveillance

The Exchange represents that trading in the Shares will be subject to the existing trading surveillances, administered by the Exchange, as well as cross-market surveillances administered by the Financial Industry Regulatory Authority (''FINRA'') on behalf of the Exchange, which are designed to detect violations of Exchange rules and applicable Federal securities laws. The Exchange represents that these procedures are adequate to properly monitor Exchange trading of the Shares in all trading sessions and to deter and detect violations of Exchange rules and Federal securities laws applicable to trading on the Exchange.[24]

[20] The Exchange represents that an authorized participant will issue execution instructions to the Trusted Agent and be responsible for all associated profit or losses. Like a traditional ETF, the authorized participant has the ability to sell the basket securities at any point during normal trading hours.

[21] According to the Exchange, under applicable provisions of the Internal Revenue Code, the authorized participant is expected to be deemed a ''substantial owner'' of the Confidential Account because it receives distributions from the Confidential Account. As a result, the Exchange states, all income, gain, or loss realized by the Confidential Account will be directly attributed to the authorized participant. The Exchange also states that, in a redemption, the authorized participant will have a basis in the distributed securities equal to the fair market value at the time of the distribution, and any gain or loss realized on the sale of those Shares will be taxable income to the authorized participant.

[22] A Fund's Custodian will provide, on a daily basis, the constituent basket file comprised of all securities plus any cash to the independent pricing agent(s) for purposes of pricing.

[23] Proposed Rule 8.900(d)(2)(C) provides that, upon notification to the Exchange by the Investment Company or its agent that (i) the prices from the multiple independent pricing sources to be validated by the Investment Company's Pricing Verification Agent differ by more than 25 basis points for 60 seconds in connection with pricing of the VIIV, or (ii) that the VIIV of a series of Managed Portfolio Shares is not being priced and disseminated in one-second intervals, as required, the Exchange will halt trading in the Managed Portfolio Shares as soon as practicable. The halt in trading would continue until the Investment Company or its agent notifies the Exchange that the prices from the independent pricing sources no longer differ by more than 25 basis points for 60 seconds or that the VIIV is being priced and disseminated as required. The Investment Company or its agent would be responsible for monitoring that the VIIV is being priced and disseminated as required and whether the prices to be validated from multiple independent pricing sources differ by more than 25 basis points for 60 seconds.

[24] The Exchange states that these surveillances generally focus on detecting securities trading outside their normal patterns, which could be indicative of manipulative or other violative activity. The Exchange represents that the Exchange or FINRA, on behalf of the Exchange, or both, will communicate as needed regarding trading in the Shares, underlying stocks, ETFs, and exchange-listed options with other markets and other entities that are members of the Intermarket Surveillance Group (''ISG''), and the Exchange or FINRA, on behalf of the Exchange, or both, may obtain trading information regarding such securities from such markets and other entities. In addition, the

Continued

The Exchange represents that the Funds' Adviser will make available daily to FINRA and the Exchange the portfolio holdings of each Fund in order to facilitate the performance of the surveillances referred to above. In addition, the Exchange states that it has a general policy prohibiting the distribution of material, non-public information by its employees.

II. Summary of Comment Letters

The Commission has received four comment letters on the proposed rule change, each of which express opposition to the proposed rule change.[25] As of the date of this order instituting proceedings, the Exchange has not submitted a response to the comments.

A. *Gastineau Letter.*[26] The commenter opposes approval of the proposed rule change and recommends imposition of a number of requirements in the event the proposed rule change and exemptive application are approved. As an initial matter, the commenter believes that the proposed selective disclosure of Fund portfolio holdings information to Trusted Agents trading on behalf of Confidential Account holders would constitute insider trading and would violate Federal securities laws.

In addition, the commenter asserts that market makers will face significant impediments to successfully arbitrage the Shares and predicts that this will lead to the Shares trading at wider bid-ask spreads and more variable premiums/discounts than actively-managed ETFs available today. First, the commenter questions the Exchange's assertion that the VIIV will provide an adequate basis for ensuring a Fund's ongoing price value alignment and secondary market trading efficiency. In evaluating the Exchange's statements regarding VIIVs, the commenter asserts that their utility should be compared not to the intraday indicative values (''IIVs'') of existing ETFs but rather to the independently derived, real-time estimates of underlying fund value that ETF market makers use today to identify arbitrage opportunities and manage their risks (''MM IIVs''). The commenter asserts that, because existing actively managed ETFs (and most index ETFs) provide full daily disclosure of their current portfolio, market makers of transparent funds have access to far better information about the current value of fund holdings than the proposed VIIVs would provide and, correspondingly, VIIVs will be significantly less precise than MM IIVs. The commenter also asserts that MM IIVs include significant information that would not be reflected in VIIVs, noting as follows:

- In calculating VIIVs, Fund securities would be valued based on the mid-point between the current national best bid and offer quotations. The commenter characterizes the bid-ask midpoint as a ''fairly crude valuation metric'' that does not capture important trading information incorporated into MM IIVs, such as the current bid-ask spread, the depth of the current order book on the bid and offer side of the market, and the predominance of current trading between bid-side and offer-side transactions.
- VIIVs would be calculated and disseminated every second and, while this interval may seem sufficient, MM IIVs are updated in fractions of a second (milliseconds or microseconds).
- The VIIV verification process would leave significant room for dissemination of erroneous values. For example, a Fund's Pricing Verification Agent would take no action to address observed discrepancies in VIIV input prices until the calculated Fund values differ by at least 25 bps for 60 seconds. The commenter characterizes that disparity as ''huge,'' asserting that it would be wider than the customary bid-ask spread of most domestic equity ETFs.
- The VIIV process would not address all potential intraday valuation errors. The commenter describes that corporate actions must be accurately reflected in the VIIV, which can be challenging, and market makers would not be able to verify that corporate actions are appropriately reflected in a Fund's VIIVs because of the non-transparent portfolio.
- The process for adjusting VIIVs in the event of trading halts in portfolio securities is cumbersome and likely to result in errors in disseminated VIIVs. Throughout a halt, which may be protracted, the Fund would continue to disseminate VIIVs that do not reflect fair values of the halted security, and therefore may vary significantly from the Fund's true underlying value at that time. The commenter asserts that MM IIVs would almost certainly arrive at a fair estimate of a Fund's current underlying value far faster than the VIIV specified process.

The commenter asserts that reliance on faulty VIIVs may expose market makers to unrecoverable losses, noting that: (1) Neither the Exchange nor its agents nor the Reporting Authority would be liable for disseminating erroneous VIIVs; and (2) the circumstances under which the independent pricing sources and the Pricing Verification Agent are legally liable for such errors are limited. According to the commenter, market makers' forced reliance on VIIVs to determine intraday Fund valuations is a source of significant incremental risk for them versus making markets in existing ETFs. The commenter predicts that this will result in the Shares trading at wider bid-ask spreads and more variable premiums and discounts to NAV than similar existing ETFs.

The commenter also criticizes the Confidential Accounts structure. The commenter asserts that, compared to the usual manner in which market makers in existing ETFs engage in arbitrage and buy and sell Creation Basket instruments, the Confidential Accounts arrangement exposes market makers to significant additional costs, risks, and lost opportunities, including:

- Less control over trade execution and trade order management when implementing portfolio hedging and Creation Unit transactions, which will result in more cost and risk, and less profit opportunity.
- No ability for market makers to use their market knowledge and market positions to enhance arbitrage profits and minimize costs.
- Reduced incentive for third-party service providers to trade expeditiously and with low market impact.
- Little or no ability for market makers to monitor trading in Confidential Accounts to ensure best execution or to evaluate trading performance.
- Forced *pro rata* hedging, which the commenter states is very often not the best hedge. Sub-optimal hedging results in less efficient arbitrage.
- Given the more-involved routing of trade instructions and trade orders that the Confidential Account structure would necessitate, the commenter states that hedging and Creation Unit instrument transactions through Confident Accounts will almost certainly take longer, on average, for a market maker to execute than similar transactions that the market maker executes internally. According to the commenter, slower executions may translate into less efficient arbitrage.
- Potentially significant explicit costs to establish and maintain Confidential Accounts.

Additionally, the commenter questions the Exchange's statements

Exchange may obtain information regarding trading in the Shares, underlying stocks, ETFs and exchange-listed options from markets and other entities that are members of ISG or with which the Exchange has in place a comprehensive surveillance sharing agreement.

[25] *See supra* note 6.

[26] The Gastineau Letter is available at: *https://www.sec.gov/comments/sr-nysearca-2017-36/nysearca201736-1773725-152542.pdf.*

regarding the efficiency and utility of statistical arbitrage. The commenter states that while market makers may be able to gain some useful information about a Fund's current composition by knowing the Fund's investment objective and tracking performance correlations over time versus a known index, the amount of portfolio information that can be gleaned using this approach is limited. The commenter states that, as a result, any portfolio hedge constructed using this information would be subject to meaningful basis risk, especially during times of market stress or volatility.

The commenter expresses concerns regarding data security, misappropriation, and misuse of a Fund's confidential portfolio information in light of the dissemination of this data across a potentially broad network of Trusted Agents, affiliated broker-dealers, and other Confidential Account service providers. The commenter also raises concerns regarding the possibility that market participants could use the VIIV to reverse-engineer the Funds' portfolio holdings, subjecting the Funds to the dilutive effects of front-running. The commenter asserts that ''it is far from a settled question that the Funds would not ever be susceptible to reverse engineering.''

B. *Broms Letter.*[27] The commenter opposes the proposed rule change. The commenter asserts that the proposed selective disclosure of confidential Fund holdings information to Trusted Agents for trading on behalf of Confidential Account holders would violate Federal securities laws. In addition, the commenter believes that the mechanism for ensuring secondary market trading efficiency in the Shares is ''unreliable'' and predicts that the Shares will likely trade at significantly wider bid-ask spreads and/or more variable premiums/discounts than existing ETFs. The commenter also expresses concerns regarding the following:

- The likelihood that the Shares' trading performance will be especially poor during periods of market stress and volatility.
- The ability of the Fund to ensure the security of confidential information disseminated to Trusted Agents.
- Potentially significant added Fund costs and risks associated with calculating, verifying, and disseminating the VIIV and associated Fund warranties.
- The potential for frequent Share trading halts.
- The likely incidence of erroneous Share trades and the absence of an Exchange program to detect and remedy such trades.
- The potential for reverse engineering of a Fund's portfolio holdings.
- The tax risk due to the Funds' distinctive in-kind redemption program.
- The costs, risk, and uncertainties to broker-dealers serving as authorized participants and non-authorized participant market makers in meeting their compliance obligations with respect to securities traded on their behalf through Confidential Accounts.

C. *Angel Letter.*[28] The commenter opposes the proposal. The commenter believes that the opaque nature of the products will make arbitrage more difficult and the added costs and risks will lead to wider deviations of the market price from the underlying asset value. In addition, the commenter raises concerns that the Funds may fare worse than traditional ETFs during times of market disruption given their opacity and the complexity of the arbitrage relationship between the Funds and the underlying securities. The commenter also expresses concern that selective disclosure of portfolio information could raise issues under Regulation FD and that the use of Confidential Accounts could raise issues under Regulation SHO.

In addition, the commenter expresses the following concerns:

- It is unclear whether a firm's risk management would have access to the contents of Confidential Accounts. If a firm's risk management does not have access to such information, the firm would be subject to too much risk, but if the firm's risk management does have access, information barriers would create compliance issues.
- Positions held in the Confidential Account not closed out by the end of the day would have to be settled, and that the settlement information would be available to settlement personnel.
- The Trusted Agents would have serious compliance burdens, and that these burdens could drive up the cost of being a Trusted Agent, which would subsequently drive up the cost of arbitrage. Higher costs and compliance risks would severely limit the number of firms willing to take on the burden of becoming Trusted Agents, and the resulting lack of competition could lead to higher fees and inferior service. In the event that there were many Trusted Agents, the likelihood of data breaches would increase.

In addition, the commenter believes that the VIIV calculations are dangerously flawed because they rely on sometimes flawed bid-ask quotes. The commenter believes that the VIIV calculations should instead be based on the last trade, and if the underlying market is closed or the underlying asset has not traded recently, then a reasonable fair value methodology should be used.

D. *Norman Letter.*[29] The commenter opposes the proposed rule change. The commenter refutes the Trust's statistical analysis that purports to demonstrate that the Funds' portfolio compositions could not be reverse engineered.[30] The commenter's analysis concludes that reverse engineering of a Fund's portfolio is in fact ''achievable with a substantial degree of accuracy.'' [31] The commenter also asserts that, without knowledge of a Fund's underlying stocks, market makers may be unable to hedge their risks, which would result in wider and more persistent spreads or the market maker choosing not to make a market in the Shares. In addition, the commenter questions the sufficiency of disseminating the VIIV at one-second intervals, given that high frequency trading takes place in milliseconds, and raises concerns about potential systems failures that may disrupt the dissemination of VIIV. Finally, the commenter also believes that selective disclosure of portfolio information to Trusted Agents would violate Federal securities laws, and expresses concern regarding the security of confidential portfolio information.

III. Proceedings to Determine Whether To Approve or Disapprove SR–NYSEArca–2017–36 and Grounds for Disapproval Under Consideration

The Commission is instituting proceedings pursuant to Section 19(b)(2)(B) of the Act [32] to determine whether the proposed rule change should be approved or disapproved. Institution of such proceedings is

[27] The Broms Letter is available at: *https://www.sec.gov/comments/sr-nysearca-2017-36/nysearca201736-1772689-152536.pdf.*

[28] The Angel Letter is available at: *https://www.sec.gov/comments/sr-nysearca-2017-36/nysearca201736-1774133-152313.pdf.*

[29] The Norman Letter is available at: *https://www.sec.gov/comments/sr-nysearca-2017-36/nysearca201736-1863492-156216.pdf.*

[30] *See* Third Amended and Restated Application for an Order under Section 6(c) of the Investment Company Act of 1940 (''1940 Act'') for exemptions from various provisions of the 1940 Act and rules thereunder (File No. 812–14405), dated May 2, 2017, at Exhibit E (''Additional Research on the Ability to Reverse Engineer the Proposed Precidian ETF,'' by Ricky Alyn Cooper, Ph.D., dated August 2015).

[31] *See* Norman Letter, Appendix One (''The Reverse Engineering of Portfolio Compositions,'' by Dr. Anthony Hayter, dated July 17, 2017).

[32] 15 U.S.C. 78s(b)(2)(B).

appropriate at this time in view of the legal and policy issues raised by the proposed rule change. Institution of proceedings does not indicate that the Commission has reached any conclusions with respect to any of the issues involved. Rather, as described below, the Commission seeks and encourages interested persons to provide comments on the proposed rule change.

Pursuant to Section 19(b)(2)(B) of the Act,[33] the Commission is providing notice of the grounds for disapproval under consideration. The Commission is instituting proceedings to allow for additional analysis of the proposed rule change's consistency with Section 6(b)(5) of the Act, which requires, among other things, that the rules of a national securities exchange be ''designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, . . . to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest.'' [34]

IV. Procedure: Request for Written Comments

The Commission requests that interested persons provide written submissions of their views, data, and arguments with respect to the issues identified above, as well as any other concerns they may have with the proposal. In particular, the Commission invites the written views of interested persons concerning whether the proposal is consistent with Section 6(b)(5) or any other provision of the Act, or the rules and regulations thereunder. Although there do not appear to be any issues relevant to approval or disapproval that would be facilitated by an oral presentation of views, data, and arguments, the Commission will consider, pursuant to Rule 19b–4, any request for an opportunity to make an oral presentation.[35]

Interested persons are invited to submit written data, views, and arguments regarding whether the proposal should be approved or disapproved by August 25, 2017. Any person who wishes to file a rebuttal to any other person's submission must file that rebuttal by September 8, 2017.

The Commission asks that commenters address the sufficiency of the Exchange's statements in support of the proposal, which are set forth in the Notice,[36] in addition to any other comments they may wish to submit about the proposed rule change. Specifically, the Commission seeks comment on the statements of the Exchange contained in the Notice, the issues raised by the commenters, and any other issues raised by the proposed rule change. In addition, the Commission seeks comment on whether the trading of the Shares would be consistent with the maintenance of fair and orderly markets. In this regard, the Commission specifically seeks comment regarding market makers' ability to make markets in the Shares and the sufficiency of the proposed VIIV as pricing information to market participants. Further, the Commission solicits comments on whether the selective disclosure of portfolio holdings to a Trusted Agent, as well as the non-transparent structure of the Funds, could result in any information asymmetry that would be inconsistent with the Act or other Federal securities laws or rules and regulations thereunder.

Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–NYSEArca–2017–36 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Numbers SR–NYSEArca–2017–36. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet 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 these filings 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–NYSEArca–2017–36 and should be submitted on or before August 25, 2017. Rebuttal comments should be submitted by September 8, 2017.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[37]

Eduardo A. Aleman,

Assistant Secretary.

[FR Doc. 2017–16402 Filed 8–3–17; 8:45 am]

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[33] *Id.*

[34] 15 U.S.C. 78f(b)(5).

[35] Section 19(b)(2) of the Act, as amended by the Securities Act Amendments of 1975, Public Law 94–29 (June 4, 1975), grants the Commission flexibility to determine what type of proceeding—either oral or notice and opportunity for written comments—is appropriate for consideration of a particular proposal by a self-regulatory organization. *See* Securities Act Amendments of 1975, Senate Comm. on Banking, Housing & Urban Affairs, S. Rep. No. 75, 94th Cong., 1st Sess. 30 (1975).

[36] *See supra* note 3.

[37] 17 CFR 200.30–3(a)(57).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–81268; File No. SR–NYSEARCA–2017–79]

Self-Regulatory Organizations; NYSE Arca, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Modify the NYSE Arca Options Fee Schedule

July 31, 2017.

Pursuant to Section 19(b)(1) [1] of the Securities Exchange Act of 1934 (the ''Act'') [2] and Rule 19b–4 thereunder,[3] notice is hereby given that, on July 20, 2017, NYSE Arca, Inc. (the ''Exchange'' or ''NYSE Arca'') 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 self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

[1] 15 U.S.C.78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to modify the NYSE Arca Options Fee Schedule (''Fee Schedule'') to add clarification and consistency, but the Exchange is not proposing any changes to its fees. The Exchange proposes to implement the fee change effective July 20, 2017. The proposed rule change is available on the Exchange's Web site at *www.nyse.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The purpose of this filing is to make a number of textual changes designed to clarify and add consistency to the Fee Schedule. The Exchange is not proposing to make any substantive changes to its current fees.

Earlier this month, July 2017, the Exchange submitted a filing that included clarifying changes to certain tables regarding Market Maker incentives (the ''MM Cleanup Filing'').[4] The first sets of proposed changes are conforming changes, which are designed to align the text used in other incentive programs described in the Fee Schedule with those modified in the MM Cleanup Filing. Specifically, these conforming changes include:

- The Exchange proposes to re-locate the reference to Endnote 15 from the beginning [sic] to the end [sic] of each of the following tables: ''Customer and Professional Customer Monthly Posting Credit Tiers and Qualifications for Executions in Penny Pilot Issues''; ''Customer and Professional Customer Incentive Program''; and [sic] ''Non-Customer Monthly Posting Credit Tiers and Qualifications for Executions in Non-Penny Pilot Issues''; ''Take Fee Discount Qualification for Penny Pilot Issues''; and ''Take Fee Discount Qualification for Non-Penny Pilot Issues'' (the ''Modified Tables''). Endnote 15 provides that the qualification thresholds set forth in the applicable tables ''[i]ncludes transaction volume from the OTP Holder's or OTP Firm's affiliates or its Appointed OFP or Appointed MM.'' [5] Consistent with this proposed change, the Exchange proposes to remove the language that appears at the end of each of the Modified Tables providing that volume of an Appointed MM or Appointed OFP may be included because it would be duplicative of text contained in Endnote 15.
- The Exchange proposes to replace reference to ''Total Industry Customer equity and ETF option average daily volume'' with ''TCADV'' (as defined in Endnote 8) [6] and to use this shorthand reference in the Modified Tables. Given that TCADV is defined in Endnote 8 and given that the ''Customer and Professional Customer Monthly Posting Credit Tiers and Qualifications for Executions in Penny Pilot Issues'' includes reference to Endnote 8, the Exchange proposes to remove the following language from this table because it is duplicative: ''Qualifications based in part on Total Industry Customer equity and ETF option average daily volume (''TCADV'').''
- In each of the Modified Tables, the Exchange proposes to replace reference to ''Posted Orders'' with ''posted interest'' and any reference to ''orders'' with ''interest'' to make clear that, where applicable, liquidity may include orders or quotes.
- For consistency, the Exchange proposes to remove any capitalization from ''issues'' in reference to ''all issues'' in the Modified Tables. The Exchange also proposes to capitalize ''Issues'' as relates to ''Penny Pilot Issues,'' in the preamble to the ''Customer and Professional Customer Monthly Posting Credit Tiers and Qualifications for Executions in Penny Pilot Issues,'' and as relates to ''non-Penny Pilot Issues,'' in the preamble to the ''Non-Customer Monthly Posting Credit Tiers and Qualifications for Executions in Non-Penny Pilot Issues.''
- The Exchange also proposes to add a comma and, where applicable, the word ''or'', to signify an alternative qualification basis in certain of the Modified Tables as well as to remove any capitalization of the word ''Plus'' as relates to any alterative qualification bases in the Modified Tables.
- The Exchange also proposes to alter the language in the Modified Tables to clarify how the credits are applied, *i.e.,* that credit is applied to ''electronic executions of [the applicable] posted interest'' in the applicable securities. For consistency and clarity, the Exchange proposes to add ''Electronic'' to, as well as to capitalize ''Non-Penny,'' in the table heading for the ''Non-Customer Monthly Posting Credit Tiers and Qualifications for Executions in Non-Penny Pilot Issues.''
- For ease of reference, the Exchange proposes to rename the ''Non-Customer Monthly Posting Credit Tiers and Qualifications for Executions in Non-Penny Pilot Issues'' to ''Non-Customer, Non-Penny Pilot Posting Credit Tiers.''

In addition to the foregoing, the Exchange also proposes to consistently utilize the term ''Customer'' to include Professional Customers, unless otherwise specified. Per the current Fee Schedule, regarding trade-related charges for standard options, the Exchange specifies that ''[u]nless Professional Customer executions are specifically delineated, such executions will be treated as Customer executions for fee purposes.'' [7] Although this language should (arguably) apply to the sections that follow, including incentive programs based on posted interest, the Exchange refers to both Customer and Professional Customer volume being counted towards the same incentives.[8] Because the Exchange treats both Professional Customer and Customer volume the same for purposes of achieving the Customer Posting Tiers, the Exchange proposes to remove reference to Professional Customer from these sections of the Fee Schedule.'' [9]

[4] *See* Securities Exchange Act Release No. 81140 (July 13, 2017), 82 FR 33194 (July 19, 2017) (SR–NYSEArca–2017–77).

[5] *See* Fee Schedule, Endnote 15.

[6] *See supra* note 4, the MM Cleanup Filing (adding definition of TCADV).

[7] *See* Fee Schedule, NYSE Arca Options: Trade-Related Changes for Standard Options. For additional clarity, the Exchange proposes to revise this sentence to put Customer in quotations and to add reference to credits. *See* proposed Fee Schedule, NYSE Arca Options: Trade-Related Changes for Standard Options (providing that ''[u]nless Professional Customer executions are specifically delineated, such executions will be treated as ''Customer'' executions for fee/credit purposes).

[8] *See id.,* Customer and Professional Customer Monthly Posting Credit Tiers and Qualifications for Executions in Penny Pilot Issues; Customer and Professional Customer Incentive Program; and Customer and Professional Customer Posting Credit Tiers In Non Penny Pilot Issues (collectively, the ''Customer Posting Tiers'').

[9] *See* proposed Fee Schedule, the Customer Posting Tiers.

Consistent with this change, the Exchange proposes the following changes to the Customer Posting Tiers:

• The Exchange proposes to re-name the ''Customer and Professional Customer Monthly Posting Credit Tiers and Qualifications for Executions in Penny Pilot Issues,'' as ''Customer Penny Pilot Posting Credit Tiers.'' Consistent with certain of the conforming changes referenced above regarding how the applicable credits are the [sic] applied, the Exchange also proposes to modify the preamble to provide that ''OTP Holders and OTP Firms meeting the qualifications below will receive the corresponding posting credit on all electronic executions of Customer posted interest in Penny Pilot Issues.'' In addition, the Exchange proposes to update cross-references to this newly named table as appears in the Firm and Broker Dealer Monthly Fee Cap.

• The Exchange proposes to add a title to signify the incentive program for ''Customer and Professional Customer Posting Credit Tiers In Non Penny Pilot Issues,'' which title would be ''Customer Posting Credit Tiers in Non-Penny Pilot Issues.'' The Exchange proposes to add a hyphen to the word ''Non Penny'' as appears in the table, for internal consistency. The Exchange also proposes to add a preamble to this table, which provides that ''OTP Holders and OTP Firms meeting the qualifications below will receive the corresponding credit on all electronic executions of Customer posted interest in Non-Penny Pilot issues,'' and to reference Endnotes 8 and 15, which describe what is included in eligible monthly volume and how that volume is calculated. Consistent with the proposed reference to Endnote 8 at the beginning of this table, which includes a description of qualifying ADV of Retail Orders of U.S. Equity Market Share on the NYSE Arca Equity Market, the Exchange proposes to remove duplicative references to Endnote 8 that appear throughout this table.

• For avoidance of doubt, the Exchange proposes to add a sentence to Endnote 8 which provides that repeats that [sic] ''[u]nless Professional Customer executions are specifically delineated, such executions will be treated as ''Customer'' executions executions [sic] in calculating qualifications for monthly posting credits or discounts.''

The Exchange also proposes to define ''Non-Customers,'' as used in the Fee Schedule, to include Firms, Broker Dealers, and Market Makers.[10] Consistent with this change, the Exchange proposes to utilize, as shorthand, the defined term Non-Customer in place of references to Firms, Broker Dealers and Market Makers.[11]

Finally, the Exchange also proposes to re-locate the Market Maker Incentive For Penny Pilot Issues; the Market Maker Incentive For Non-Penny Pilot Issues; and the MM Tiers (collectively, the ''MM Tables''), without altering the substance of these tables.[12] Specifically, the Exchange proposes to move the MM Tables immediately below the current Discount in Take Liquidity Fees for Professional Customer, Market Maker, Firm, and Broker Dealer Liquidity Removing Orders,[13] which would place the MM Tables Immediately before the recently modified ''Market Maker Penny Pilot and SPY Posting Credit Tiers.'' [14] The Exchange believes moving table applicable to certain participants adjacent to each other would add to the clarity of the Fee Schedule and make it easier to navigate and comprehend.

To the extent not specifically noted herein, the Exchange has also corrected certain typographical errors (such as missing hyphens or redundant endnote markings) as well as streamlined certain text to add clarity and transparency to the Fee Schedule.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with Section 6(b) of the Act,[15] in general, and furthers the objectives of Sections 6(b)(4) and (5) of the Act,[16] in particular, because it provides for the equitable allocation of reasonable dues, fees, and other charges among its members, issuers and other persons using its facilities and does not unfairly discriminate between customers, issuers, brokers or dealers. There are no changes to actual fees in this filing.

The Exchange believes the proposed non-substantive changes to the Fee Schedule are reasonable, equitable, and not unfairly discriminatory because the changes would add clarity, transparency and internal consistency to the Fee Schedule making it easier to navigate and comprehend, which would benefit all market participants.

For these reasons, the Exchange believes that the proposal is consistent with the Act.

B. Self-Regulatory Organization's Statement on Burden on Competition

In accordance with Section 6(b)(8) of the Act,[17] the Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The Exchange believes that the proposed textual changes are not intended to have any impact on competition, but instead are designed to make the Fee Schedule easier for market participants to navigate and digest, which is in the public interest.

The Exchange notes that it operates in a highly competitive market in which market participants can readily favor competing venues. In such an environment, the Exchange must continually review, and consider adjusting, its fees and credits to remain competitive with other exchanges. For the reasons described above, the Exchange believes that the proposed rule change reflects this competitive environment.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change is effective upon filing pursuant to Section 19(b)(3)(A) [18] of the Act and subparagraph (f)(2) of Rule 19b–4 [19] thereunder, because it establishes a due, fee, or other charge imposed by the Exchange.

At any time within 60 days of the filing of such proposed rule change, the Commission summarily may temporarily suspend such rule change if

[10] *See* proposed Fee Schedule, NYSE Arca Options: Trade-Related Changes for Standard Options (providing that ''Firms, Broker Dealers, and Market Makers are collectively referred to herein as ''Non-Customers'').

[11] *See* proposed Fee Schedule, Discount in Take Liquidity Fees for Professional Customer and Non-Customer Liquidity Removing Interest; Take Fee Discount Qualification for Penny Pilot Issues (providing alternative threshold of at least 2.00% of TCADV from Professional Customer and Non-Customer Liquidity Removing interest in all issues.''

[12] *See supra* note 4, the MM Cleanup Filing (includes modifications to the text of the MM Tables).

[13] *See supra* note 10 (proposing to re-name this table).

[14] *See supra* note 4, the MM Cleanup Filing (includes modifications to the text of the MM Tables).

[15] 15 U.S.C. 78f(b).

[16] 15 U.S.C. 78f(b)(4) and (5).

[17] 15 U.S.C. 78f(b)(8).

[18] 15 U.S.C. 78s(b)(3)(A).

[19] 17 CFR 240.19b–4(f)(2).

it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings under Section 19(b)(2)(B) [20] of the Act to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–NYSEArca-2017–79 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–NYSEArca–2017–79. 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–NYSEArca–2017–79, and should be submitted on or before August 25, 2017.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[21]

Eduardo A. Aleman,

Assistant Secretary.

[FR Doc. 2017–16403 Filed 8–3–17; 8:45 am]

BILLING CODE 8011–01–P

[20] 15 U.S.C. 78s(b)(2)(B).

[21] 17 CFR 200.30–3(a)(12).

SMALL BUSINESS ADMINISTRATION

Reporting and Recordkeeping Requirements Under OMB Review

AGENCY: Small Business Administration.

ACTION: 30-Day notice.

SUMMARY: The Small Business Administration (SBA) is publishing this notice to comply with requirements of the Paperwork Reduction Act (PRA), which requires agencies to submit proposed reporting and recordkeeping requirements to OMB for review and approval, and to publish a notice in the **Federal Register** notifying the public that the agency has made such a submission. This notice also allows an additional 30 days for public comments.

DATES: Submit comments on or before September 5, 2017.

ADDRESSES: Comments should refer to the information collection by name and/or OMB Control Number and should be sent to: *Agency Clearance Officer,* Curtis Rich, Small Business Administration, 409 3rd Street SW., 5th Floor, Washington, DC 20416; and *SBA Desk Officer,* Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT: Curtis Rich, Agency Clearance Officer, (202) 205–7030 *curtis.rich@sba.gov.*

Copies: A copy of the Form OMB 83–1, supporting statement, and other documents submitted to OMB for review may be obtained from the Agency Clearance Officer.

SUPPLEMENTARY INFORMATION: The Small Business Administration requires information to be disclosed to the buyer when a secondary market loan is transferred from one investor to another. This information includes a constant annual prepayment rate based upon the seller's analysis of prepayment histories of SBA guaranteed loans with similar maturities. Additionally, information is required on the terms, conditions and yield of the security being transferred.

(1) *Title:* Form of Detached Assignment for U.S. Small Business Administration Loan Pool or Guaranteed Interest Certificate.

Description of Respondents: Secondary Market Lenders.

Estimated Annual Responses: 7,500.

Estimated Annual Hour Burden: 11,250.

Curtis B. Rich,

Management Analyst.

[FR Doc. 2017–16406 Filed 8–3–17; 8:45 am]

BILLING CODE 8025–01–P

DEPARTMENT OF STATE

[Public Notice: 10071]

Notice of Public Meeting of the International Telecommunication Advisory Committee and Preparations for Upcoming International Telecommunications Meetings

This notice announces a meeting of the Department of State's International Telecommunication Advisory Committee (ITAC). The ITAC will meet on September 07, 2017 at 2:00 p.m. ET at 1120 20th St., 10th Floor, Washington, DC 20036. At this meeting, the ITAC will discuss preparations for the International Telecommunication Union (ITU) 2018 Plenipotentiary Conference (PP–18), review the results of recent multilateral meetings, and discuss preparations for upcoming multilateral meetings at ITU, the Organization for Economic Cooperation and Development (OECD), and the Asia Pacific Economic Cooperation (APEC). In **Federal Register** Notice 9920 [1] published on March 20, 2017, the Department of State sought advice from stakeholders and interested parties to inform its upcoming preparations for PP–18. No written comments were received.

The meeting will focus on the following topics:

- Initiation of 2018 ITU Plenipotentiary Conference (PP–18) Preparatory Process
- Results of Recent Multilateral Meetings
  - ITU Council-17
  - Inter-American Telecommunication Commission (CITEL)
  - Permanent Consultative Committee on Telecommunication/ICT PCC–I

[1] *https://www.federalregister.gov/documents/2017/03/20/2017-05456/notice-of-public-meeting-of-the-international-telecommunication-advisory-committee-and-preparations.*

- Permanent Consultative Committee on Radiocommunication (PCC–II)

- Preparations for Upcoming Multilateral Activities
  - ITU Council Working Groups and Experts Group on International Telecommunication Regulations (ITRs)
  - ITU World Telecommunication Development Conference (WTDC)
  - OECD Committee on Digital Economy Policy—November 20–24, 2017
  - APEC Telecommunications Working Group (APEC TEL 56)—December 11–15, 2017

PP–18 will take place in Dubai, United Arab Emirates, from October 29 to November 17, 2018. A Plenipotentiary Conference, which takes place every four years, is the highest policy-making body of the Union. PP–18 is expected to determine the overall policy direction of the ITU; adopt the strategic and financial plans for the next four years; elect the 48 members of Council, 12 members of the Radio Regulations Board, and five elected officials of the ITU; and consider and adopt, if appropriate, modifications to the ITU Constitution and Convention.

Attendance at the ITAC meeting is open to the public as seating capacity allows. The public will have an opportunity to provide comments at this meeting at the invitation of the chair.

Further details on this ITAC meeting will be announced on the Department of State's email list, *ITAC@lmlist.state.gov.* Use of the ITAC list is limited to meeting announcements and confirmations, distribution of agendas and other relevant meeting documents. The Department of State welcomes any U.S. citizen or legal permanent resident to remain on or join the ITAC listserv by registering by email via *ITAC@state.gov* and providing his or her name, email address, telephone contact and the company, organization, or community that he or she is representing, if any. Persons wishing to request reasonable accommodation during the meeting should send their requests to *ITAC@state.gov* no later than August 28, 2017. Requests made after that time will be considered, but might not be able to be satisfied.

FOR FURTHER INFORMATION CONTACT: Please send all inquiries to *ITAC@state.gov.*

Douglas C. May,

Acting Coordinator, International Communications and Information Policy, Department of State.

[FR Doc. 2017–16242 Filed 8–3–17; 8:45 am]

BILLING CODE 4710–AE–P

SURFACE TRANSPORTATION BOARD

[Docket No. FD 36123]

The Indiana Rail Road Company and CSX Transportation Inc.—Joint Relocation Project Exemption—Terre Haute, Ind.

On July 21, 2017, the Indiana Rail Road Company (INRD) filed a verified notice of exemption under 49 CFR 1180.2(d)(5) to enter into a joint project with CSX Transportation, Inc. (CSXT), involving the relocation of a segment of INRD's rail line in Terre Haute, Ind.

The purpose of the joint relocation project is to allow the removal of two crossing diamonds at Belt Junction, to eliminate conflicting INRD and CSXT train movements at both Belt Junction and Spring Hill, and to improve the efficiency of INRD and CSXT operations in the Terre Haute area. The joint relocation project notice covers the following actions:

(1) INRD will acquire overhead trackage rights on CSXT's Baker Siding extending from the connection with INRD's line at approximately CSXT Milepost 0ZA 181.1 at Belt Junction to the connection with INRD's line at approximately CSXT Milepost 0ZA 182.1 at Spring Hill, a distance of approximately 1.0 miles in Terre Haute.

(2) INRD will abandon its Chicago Subdivision line extending from approximately INRD Milepost 181.5 to approximately INRD Milepost 182.03 (the INRD Line), including the northeastern leg of the wye track to the Hulman Lead, a total distance of approximately 0.85 miles in the vicinity of Belt Junction. The diamond crossings of CSXT's CE&D Subdivision at Belt Junction at CSXT Milepost 0ZA 181.1 and the immediately adjacent INRD trackage will be removed. The INRD Line between the end of the track removal at Belt Junction and the connection to the Hulman Lead will remain in place as unregulated trackage pursuant to 49 U.S.C. 10906 and used solely to turn equipment.

INRD states that it does not serve any shippers on the INRD Line, and existing service to shippers on INRD's Hulman Lead will be preserved. INRD also states that the proposed relocation will improve the operation of INRD's through trains in the area, which will avoid two crossings of CSXT's CE&D Subdivision and interference from conflicting CSXT train movements. INRD argues that no shippers will be adversely affected by this relocation or lose access to any rail service currently provided by INRD.

The Board will exercise jurisdiction over the abandonment, construction, or sale components of a joint relocation project, and require separate approval or exemption, only where the removal of track affects service to shippers or the construction of new track or transfer of existing track involves expansion into new territory, or a change in existing competitive situations. *See City of Detroit* v. *Canadian Nat'l Ry.,* 9 I.C.C.2d 1208 (1993), *aff'd sub nom. Detroit/Wayne Cty. Port Auth.* v. *ICC,* 59 F.3d 1314 (D.C. Cir. 1995); *Flats Indus. R.R. & Norfolk S. Ry.—Joint Relocation Project Exemption—in Cleveland, Ohio,* FD 34108 (STB served Nov. 15, 2001). Line relocation projects may embrace trackage rights transactions such as the one involved here. *See Detroit, Toledo & Ironton R.R.—Trackage Rights—Between Wash. Court House & Greggs, Ohio—Exemption,* 363 I.C.C. 878 (1981).

Under these standards, the incidental abandonment and trackage rights components require no separate approval or exemption when the relocation project, as here, will not disrupt service to shippers and thus qualifies for the class exemption at 49 CFR 1180.2(d)(5).

As a condition to this exemption, any employees affected by the trackage rights will be protected by the conditions imposed in *Norfolk & Western Railway—Trackage Rights—Burlington Northern, Inc.,* 354 I.C.C. 605 (1978), as modified in *Mendocino Coast Railway—Lease & Operate—California Western Railroad,* 360 I.C.C. 653 (1980).

The transaction may be consummated on or after August 20, 2017, the effective date of the exemption (30 days after the verified notice was filed).

If the notice contains false or misleading information, the exemption is void ab initio. Petitions to revoke the exemption under 49 U.S.C. 10502(d) may be filed at any time. The filing of a petition to revoke will not automatically stay the transaction. Petitions to stay must be filed by August 11, 2017 (at least seven days before the exemption becomes effective).

An original and 10 copies of all pleadings, referring to Docket No. FD 36123, must be filed with the Surface Transportation Board, 395 E Street SW., Washington, DC 20423–0001. In addition, a copy of each pleading must be served on Thomas J. Litwiler, Fletcher & Sippel LLC, 29 North Wacker Drive, Suite 920, Chicago, IL 60606–2832.

Board decisions and notices are available on our Web site at *WWW.STB.GOV.*

Decided: August 1, 2017.

By the Board, Rachel D. Campbell, Director, Office of Proceedings.

Rena Laws-Byrum,

Clearance Clerk.

[FR Doc. 2017–16433 Filed 8–3–17; 8:45 am]

BILLING CODE 4915–00–P

OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE

[Docket Number USTR–2017–0012]

Request for Comments and Notice of Public Hearing Concerning Russia's Implementation of Its WTO Commitments

AGENCY: Office of the United States Trade Representative.

ACTION: Notice and request for comments.

SUMMARY: The interagency Trade Policy Staff Committee (TPSC) will convene a public hearing and seeks comments to assist the Office of the United States Trade Representative (USTR) in the preparation of its annual report to Congress on Russia's implementation of its obligations as a member of the World Trade Organization (WTO).

DATES:

September 22, 2017: Deadline for filing a summary of testimony and requests to appear at the September 28, 2017 public hearing, and for submitting public comments.

September 28, 2017: The TPSC will convene a public hearing on Russia's implementation of its obligations as a member of the WTO at 9:30 a.m. in Rooms 1 & 2, 1724 F Street NW., Washington, DC 20508.

ADDRESSES: USTR strongly prefers electronic submissions made through the Federal eRulemaking Portal: *http://www.regulations.gov.* Follow the instructions for submitting comments in section 3 below. The docket number is USTR–2017–0012. For alternatives to on-line submissions, please contact Yvonne Jamison, Trade Policy Staff Committee, at (202) 395–3475.

FOR FURTHER INFORMATION CONTACT: For procedural questions concerning written comments or participating in the public hearing, contact Yvonne Jamison at (202) 395–3475. Direct all other questions regarding this notice to Betsy Hafner, Deputy Assistant United States Trade Representative for Russia and Eurasia, at (202) 395–9124.

SUPPLEMENTARY INFORMATION:

1. Background

Russia became a member of the WTO on August 22, 2012, and on December 21, 2012, following the termination of the application of the Jackson-Vanik amendment to Russia and the extension of permanent normal trade relations to the products of Russia, the United States and Russia both filed letters with the WTO withdrawing their notices of non-application and consenting to have the WTO Agreement apply between them. In accordance with section 201(a) of the Russia and Moldova Jackson-Vanik Repeal and Sergei Magnitsky Rule of Law Accountability Act of 2012 (Pub. L. 112–208), USTR is required to submit, by December 21st of each year, a report to Congress on the extent to which Russia is implementing the WTO Agreement, including the Agreement on the Application of Sanitary and Phytosanitary Measures and the Agreement on Trade Related Aspects of Intellectual Property Rights. The report also must assess Russia's progress on acceding to the Government Procurement Agreement (GPA) and the Information Technology Agreement, the latter of which Russia implemented fully in 2016. In addition, to the extent that USTR finds that Russia is not implementing fully the WTO Agreement or is not making adequate progress in acceding to the GPA, USTR must describe in the report the actions it plans to take to encourage Russia to improve its implementation and/or increase its accession efforts. In accordance with section 201(a), and to assist it in preparing this year's report, the TPSC is soliciting comments on these issues.

The terms of Russia's accession to the WTO are contained in the Marrakesh Agreement Establishing the World Trade Organization and the Protocol on the Accession of the Russian Federation to the WTO (including its annexes) (Protocol). The Report of the Working Party on the Accession of the Russian Federation (Working Party Report) provides detail and context to the commitments listed in the Protocol. You can find the Protocol and Working Party Report on USTR's Web site at *https://ustr.gov/node/5887* or on the WTO Web site at *http://docsonline.wto.org* (document symbols: WT/ACC/RUS/70, WT/MIN(11)/2, WT/MIN(11)/24, WT/L/839, and WT/ACC/RUS/70/Add.1, WT/ACC/RUS/70/Add.2.

2. Public Comments and Hearing

USTR must receive written comments no later than 11:59 p.m. on Friday, September 22, 2017. USTR invites written comments and/or oral testimony on Russia's implementation of the commitments made in connection with its accession to the WTO, including, but not limited to, commitments in the following areas:

a. Import regulation (*e.g.,* tariffs, tariff-rate quotas, quotas, import licenses).

b. Export regulation.

c. Subsidies.

d. Standards and technical regulations.

e. Sanitary and phytosanitary measures.

f. Trade-related investment measures.

g. Taxes and charges levied on imports and exports.

h. Other internal policies affecting trade.

i. Intellectual property rights (including intellectual property rights enforcement).

j. Services.

k. Rule of law issues (*e.g.,* transparency, judicial review, uniform administration of laws and regulations).

l. Trade-related investment measures.

m. Other WTO commitments.

The TPSC will convene a public hearing on Thursday, September 28, 2017, in Rooms 1 & 2, 1724 F Street NW., Washington, DC 20508. We must receive your written requests to present oral testimony at the hearing and a summary of that testimony by noon on by 11:59 p.m. on Friday, September 22, 2017. You must make the intent to testify notification in the ''Type Comment'' field under docket number USTR–2017–0012 on the *www.regulations.gov* Web site and you should include the name, address, telephone number and email address, if available, of the person presenting the testimony. You should attach a summary of the testimony by using the ''Upload File'' field. The name of the file also should include who will be presenting the testimony. Remarks at the hearing should be limited to no more than five minutes to allow for possible questions from the TPSC.

You should submit all documents in accordance with the instructions in section 3 below.

3. Requirements for Submissions

In order to be assured of consideration, we must receive your written comments in English by 11:59 p.m. on Friday, September 22, 2017. USTR strongly encourages commenters to make on-line submissions, using the *www.regulations.gov* Web site. On the first page of the submission, please identify it as ''Russia's Implementation of its WTO Commitments.''

To submit comments via *www.regulations.gov,* enter docket number USTR–2017–0012 on the home page and click ''search.'' The site will provide a search-results page listing all documents associated with this docket. Find a reference to this notice and click on the link entitled ''Comment Now!''

For further information on using the *www.regulations.gov* Web site, please consult the resources provided on the Web site by clicking on ''How to Use Regulations.gov'' on the bottom of the home page. We will not accept hand-delivered submissions.

The *www.regulations.gov* Web site allows users to submit comments by filling in a ''Type Comment'' field or by attaching a document using an ''Upload File'' field. USTR prefers that you submit comments in an attached document. If you attach a document, it is sufficient to type ''See attached'' in the ''Type Comment'' field. USTR prefers submissions in Microsoft Word (.doc) or Adobe Acrobat (.pdf). If you use an application other than those two, please indicate the name of the application in the ''Type Comment'' field.

For any comments submitted electronically containing business confidential information, the file name of the business confidential version should begin with the characters ''BC''. Any page containing business confidential information must be clearly marked ''BUSINESS CONFIDENTIAL'' on the top of that page. Filers of submissions containing business confidential information also must submit a public version of their comments that we will place in the docket for public inspection. The file name of the public version should begin with the character ''P''. The ''BC'' and ''P'' should be followed by the name of the person or entity submitting the comments. Filers submitting comments containing no business confidential information should name their file using the name of the person or entity submitting the comments.

Please do not attach separate cover letters to electronic submissions; rather, include any information that might appear in a cover letter in the comments themselves. Similarly, to the extent possible, please include any exhibits, annexes, or other attachments in the same file as the submission itself, not as separate files.

As noted, USTR strongly urges submitters to file comments through *www.regulations.gov.* You must make any alternative arrangements with Yvonne Jamison in advance of transmitting a comment. You can contact Ms. Jamison at (202) 395–3475. General information concerning USTR is available at *www.ustr.gov.*

We will post comments in the docket for public inspection, except business confidential information. You can view comments on the *www.regulations.gov* Web site by entering the relevant docket number in the search field on the home page.

Edward Gresser,

Chair, Trade Policy Staff Committee, Office of the United States Trade Representative.

[FR Doc. 2017–16389 Filed 8–3–17; 8:45 am]

BILLING CODE 3290–F7–P

DEPARTMENT OF TRANSPORTATION

Federal Railroad Administration

[Docket Number FRA–2010–0059]

Kansas City Southern Railway Company's Request for Positive Train Control Safety Plan Approval and System Certification

AGENCY: Federal Railroad Administration (FRA), U.S. Department of Transportation (DOT).

ACTION: Notice of availability and request for comments.

SUMMARY: This document provides the public with notice that the Kansas City Southern Railway Company (KCS) submitted to FRA its Positive Train Control Safety Plan (PTCSP) Version 1.0, dated June 30, 2017, on FRA's Secure Information Repository site on June 30, 2017. KCS asked FRA to approve its PTCSP and issue a Positive Train Control (PTC) System Certification for KCS' Interoperable Electronic Train Management System (I–ETMS).

DATES: FRA will consider communications received by September 5, 2017 before taking final action on the PTCSP. FRA may consider comments received after that date if practicable.

ADDRESSES: All communications concerning this proceeding should identify Docket Number 2010–0059 and may be submitted by any of the following methods:

- *Web site: http://www.regulations.gov.* Follow the online instructions for submitting comments.
- *Fax:* 202–493–2251.
- *Mail:* Docket Operations Facility, U.S. Department of Transportation, 1200 New Jersey Avenue SE., W12–140, Washington, DC 20590.
- *Hand Delivery:* 1200 New Jersey Avenue SE., Room W12–140, Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Dr. Mark Hartong, Senior Scientific Technical Advisor, at (202) 493–1332, or *Mark.Hartong@dot.gov;* or Mr. David Blackmore, Staff Director, Positive Train Control Division, at (312) 835–3903, or *David.Blackmore@dot.gov.*

SUPPLEMENTARY INFORMATION: In its PTCSP, KCS asserts that the I–ETMS system it is implementing is designed as a vital overlay PTC system as defined in 49 CFR 236.1015(e)(2). The PTCSP describes KCS' I–ETMS implementation and the associated I–ETMS safety processes, safety analyses, and test, validation, and verification processes used during the development of I–ETMS. The PTCSP also contains KCS' operational and support requirements and procedures.

KCS' PTCSP and the accompanying request for approval and system certification are available for review online at *www.regulations.gov* (Docket Number FRA–2010–0059) and in person at DOT's Docket Operations Facility, 1200 New Jersey Avenue SE., W12–140, Washington, DC 20590. The Docket Operations Facility is open from 9 a.m. to 5 p.m., Monday through Friday, except Federal holidays.

Interested parties are invited to comment on the PTCSP by submitting written comments or data. During its review of the PTCSP, FRA will consider any comments or data submitted. However, FRA may elect not to respond to any particular comment and, under 49 CFR 236.1009(d)(3), FRA maintains the authority to approve or disapprove the PTCSP at its sole discretion. FRA does not anticipate scheduling a public hearing regarding KCS' PTCSP because the circumstances do not appear to warrant a hearing. If any interested party desires an opportunity for oral comment, the party should notify FRA in writing before the end of the comment period and specify the basis for his or her request.

Privacy Act Notice

Anyone can search the electronic form of any written communications and comments received into any of our dockets by the name of the individual submitting the comment (or signing the document, if submitted on behalf of an association, business, labor union, etc.). Under 49 CFR 211.3, FRA solicits comments from the public to better inform its decisions. DOT posts these comments, without edit, including any personal information the commenter provides, to *www.regulations.gov,* as described in the system of records notice (DOT/ALL–14 FDMS), which you can review at *https://www.transportation.gov/privacy. See https://www.regulations.gov/privacyNotice* for the privacy notice of *regulations.gov.*

Issued in Washington, DC, on July 31, 2017.

Robert C. Lauby,

Associate Administrator for Railroad Safety, Chief Safety Officer.

[FR Doc. 2017–16412 Filed 8–3–17; 8:45 am]

BILLING CODE 4910–06–P

DEPARTMENT OF TRANSPORTATION

Pipeline and Hazardous Materials Safety Administration

Hazardous Materials: Notice of Applications for Special Permits

AGENCY: Pipeline and Hazardous Materials Safety Administration (PHMSA), DOT.

ACTION: Notice of actions on special permit applications.

SUMMARY: In accordance with the procedures governing the application for, and the processing of, special permits from the Department of Transportation's Hazardous Material Regulations, notice is hereby given that the Office of Hazardous Materials Safety has received the application described herein.

DATES: Comments must be received on or before September 5, 2017.

ADDRESSES: You should address comments to: Record Center, Pipeline and Hazardous Materials Safety Administration U.S. Department of Transportation Washington, DC 20590.

Comments should refer to the application number and be submitted in triplicate. If confirmation of receipt of comments is desired, include a self-addressed stamped postcard showing the special permit number.

FOR FURTHER INFORMATION CONTACT: Ryan Paquet, Director, Office of Hazardous Materials Approvals and Permits Division, Pipeline and Hazardous Materials Safety Administration, U.S. Department of Transportation, East Building, PHH–30, 1200 New Jersey Avenue Southeast, Washington, DC 20590–0001, (202) 366–4535.

SUPPLEMENTARY INFORMATION: Copies of the applications are available for inspection in the Records Center, East Building, PHH–30, 1200 New Jersey Avenue Southeast, Washington DC or at *http://regulations.gov.*

This notice of receipt of applications for special permit is published in accordance with Part 107 of the Federal hazardous materials transportation law (49 U.S.C. 5117(b); 49 CFR 1.53(b)).

Issued in Washington, DC, on July 28, 2017.

Donald Burger,

Chief, Office of the Special Permits and Approvals.

Application No.	Docket No.	Applicant	Regulation(s) affected	Nature of the special permits thereof
SPECIAL PERMITS DATA				
9649–M		Department of Defense (Military Surface Deployment & Distribution Command).	172.403(a), 172.403(b), 172.403(c), 172.403(f), 172.403(g)(2), 172.403(g)(3), 172.406(e), 172.203(d)(3), 172.203(d)(5), 172.300(a), 172.301(d), 172.310(a), 172.310(b), 172.310(c), 173.422(a)(1), 173.426(b), 173.426(c), 173.426(d), 173.421(b), 173.421(d).	To modify the special permit to authorize the addition of a Division 1.3C explosive.
11263–M		Lone Star Specialties LLC.	173.213(c)	To modify the special permit to authorize the transportation in commerce of ''flaked'' coal tar pitch in polypropylene bags that are not UN certified.
16536–M		FIBA Technologies, Inc	178.37(k)(1), 178.45(i)(1)	To authorize a reduction in the tensile test specimens from 2 to 1 as is permitted by ISO 11120.
20401–N		ATK Launch Systems Inc.	178.935(c)(1)	To authorize the transportation in commerce of UN50D packagings that meet the requirements for Large Packagings, except as provided herein.
20441–N		Spaceflight, Inc	173.185(a)	To authorize the transportation in commerce of low production lithium ion batteries contained in equipment via cargo-only aircraft.
20453–N		LG Chem	172.101 Column (9B)	To authorize the transportation in commerce of lithium ion batteries in excess of 35 kg by cargo-only aircraft.
20488–N		Saint Louis University	173.196	To authorize the transportation in commerce of Category B Infectious Substances in non-specification packaging.
20489–N		ILC Dover LP	173.56	To request approval of Class 1 materials.

[FR Doc. 2017–16443 Filed 8–3–17; 8:45 am]

BILLING CODE 4909–60–P

DEPARTMENT OF TRANSPORTATION

Pipeline and Hazardous Materials Safety Administration

Hazardous Materials: Notice of Applications for Special Permits

AGENCY: Pipeline and Hazardous Materials Safety Administration (PHMSA), DOT.

ACTION: List of Applications for Special Permits.

SUMMARY: In accordance with the procedures governing the application for, and the processing of, special permits from the Department of Transportation's Hazardous Material Regulations, notice is hereby given that the Office of Hazardous Materials Safety has received the application described herein. Each mode of transportation for which a particular special permit is requested is indicated by a number in the ''Nature of Application'' portion of the table below as follows: 1—Motor vehicle, 2—Rail freight, 3—Cargo vessel, 4—Cargo aircraft only, 5—Passenger-carrying aircraft.

DATES: Comments must be received on or before September 5, 2017.

ADDRESSES: You should address comments to: Record Center, Pipeline and Hazardous Materials Safety Administration, U.S. Department of Transportation, Washington, DC 20590.

Comments should refer to the application number and be submitted in triplicate. If confirmation of receipt of comments is desired, include a self-addressed stamped postcard showing the special permit number.

FOR FURTHER INFORMATION CONTACT: Ryan Paquet, Director, Office of Hazardous Materials Approvals and Permits Division, Pipeline and Hazardous Materials Safety Administration, U.S. Department of Transportation, East Building, PHH–30, 1200 New Jersey Avenue Southeast, Washington, DC 20590–0001, (202) 366–4535.

SUPPLEMENTARY INFORMATION: Copies of the applications are available for inspection in the Records Center, East Building, PHH–30, 1200 New Jersey Avenue Southeast, Washington, DC or at *http://regulations.gov.*

This notice of receipt of applications for special permit is published in accordance with Part 107 of the Federal hazardous materials transportation law (49 U.S.C. 5117(b); 49 CFR 1.53(b)).

Issued in Washington, DC, on July 28, 2017.

Donald Burger,

Chief, Office of the Special Permits and Approvals.

Application No.	Docket No.	Applicant	Regulation(s) affected	Nature of the special permits thereof
SPECIAL PERMITS DATA				
20492–N		Exal Corporation	178.33–7(a), 178.33a–7(a)	To authorize the transportation in commerce of 2P and 2Q receptacles with a minimum wall thickness less that what is required by the HMR. (Modes 1, 2, 3, 4, 5).
20493–N		Tesla, Inc	172.101 Column (9B), 173.185(b).	To authorize the transportation in commerce of lithium ion batteries exceeding 35 kg net weight by cargo-only aircraft. (Mode 4).
20498–N		Lighting Resources, LLC.	172.101, 172.102(c), 172.301(c), 173.185(a)(1), 173.185(c), 173.185(d), 173.22(a).	To authorize the manufacture, marking, sale and use of specifically designed packagings for the transportation in commerce of certain batteries and cells without shipping papers, and certain marking and labeling when transported for recycling or disposal. (Modes 1, 2).
20501–N		Rota Aviation Company, LLC.	173.219(c)(5), 175.10(a)(11)	To authorize the transportation in commerce of life saving appliances aboard passenger-carrying aircraft by passenger and crew. (Mode 5).
20502–N		Spencer Composites Corporation.	173.302(a), 173.304(a)	To authorize the manufacture, mark, sale, and use of non-DOT specification cylinders for the transportation of certain hazardous materials in commerce. (Modes 1, 2, 3, 4).
20503–N		Dyno Nobel Inc	177.835(a), 177.835(c)(3), 177.848(e)(2), 177.848(g)(3).	To authorize the transportation in commerce of certain oxidizing materials with certain Class 1 and Class 8 materials under alternative segregation requirements. (Mode 1).
20504–N		A123 Systems LLC	172.101 Column (9B), 173.185(b).	To authorize the transportation in commerce of lithium ion batteries in excess of 35 kg net weight by cargo-only aircraft. (Mode 4).
20507–N		Energy, United States Dept of.	173.302(a)	To authorize the transportation in commerce of non-DOT specification cylinders containing compressed hydrogen. (Mode 1).
20511–N		Armotech s.r.o	107.807(b)(1), 173.301(a)(1), 173.302(a)(1), 173.302(f)(1), 173.302(f)(2), 178.71(q), 178.71(t).	To authorize the transportation in commerce of non-DOT specification cylinders containing oxygen. (Modes 1, 2, 3, 4, 5).

[FR Doc. 2017–16445 Filed 8–3–17; 8:45 am]

BILLING CODE 4909–60–P

DEPARTMENT OF TRANSPORTATION

Pipeline and Hazardous Materials Safety Administration

Hazardous Materials: Notice of Applications for Special Permits

AGENCY: Pipeline and Hazardous Materials Safety Administration (PHMSA), DOT.

ACTION: List of applications for modification of special permits.

SUMMARY: In accordance with the procedures governing the application for, and the processing of, special permits from the Department of Transportation's Hazardous Material Regulations, notice is hereby given that the Office of Hazardous Materials Safety has received the application described herein. Each mode of transportation for which a particular special permit is requested is indicated by a number in the ''Nature of Application'' portion of the table below as follows: 1—Motor vehicle, 2—Rail freight, 3—Cargo vessel, 4—Cargo aircraft only, 5—Passenger-carrying aircraft.

DATES: Comments must be received on or before August 21, 2017.

ADDRESSES: You should address comments to: Record Center, Pipeline and Hazardous Materials Safety Administration, U.S. Department of Transportation, Washington, DC 20590.

Comments should refer to the application number and be submitted in triplicate. If confirmation of receipt of comments is desired, include a self-addressed stamped postcard showing the special permit number.

FOR FURTHER INFORMATION CONTACT: Ryan Paquet, Director, Office of Hazardous Materials Approvals and Permits Division, Pipeline and Hazardous Materials Safety Administration, U.S. Department of Transportation, East Building, PHH–30, 1200 New Jersey Avenue Southeast, Washington, DC 20590–0001, (202) 366–4535.

SUPPLEMENTARY INFORMATION: Copies of the applications are available for inspection in the Records Center, East Building, PHH–30, 1200 New Jersey Avenue Southeast, Washington DC or at *http://regulations.gov.*

This notice of receipt of applications for special permit is published in accordance with Part 107 of the Federal hazardous materials transportation law (49 U.S.C. 5117(b); 49 CFR 1.53(b)).

Issued in Washington, DC, on July 28, 2017.

Donald Burger,

Chief, Office of the Special Permits and Approvals.

Application No.	Docket No.	Applicant	Regulation(s) affected	Nature of the special permits thereof
SPECIAL PERMITS DATA				
7657–M		Welker, Inc	173.201, 173.202, 173.203, 173.301(f)(2), 173.304(a), 177.840(a)(1).	To modify the special permit to clarify authorized uses of cylinders under its authorization. (Modes 1, 2, 3, 4).
11054–M		Welker, Inc	173.201(c), 173.202(c), 173.203(c), 173.301(f)(2), 173.302a(a)(1), 173.304a(a)(1), 173.304a(d)(3)(i), 177.840(a)(1).	To modify the special permit to clarify authorized uses of cylinders under its authorization. (Modes 1, 2, 3, 4).
11352–M		Pepsico Puerto Rico, Inc	172.200, 172.300, 172.400, 172.500	To modify the special permit to authorize an additional Division 6.1 material. (Mode 1).
11516–M		Chemtronics Inc	Part 172 Subparts C, E, F, 173.304a(a), Part 174, Part 177.	To modify the special permit to authorize additional Division 2.1 hazmat to be transported. (Modes 1, 2, 3, 4).
13027–M		Ernest Hernandez	173.202, 173.203, 173.241, 173.242, 173.243.	To modify the special permit to authorize the adding of additional Class 3 hazmat. (Mode 1).
15238–M		Reeder Flying Service, Inc	172.101 Column (9B), 172.200, 172.301(c), 172.204(c)(3), 173.27(b)(2), 175.30(a)(1), 175.75, Part 178.	To modify the special permit to add and remove items from the authorized hazmat to be transported. (Mode 4).
16011–M		Americase, Inc	172.200, 172.400, 172.300, 172.500, 172.600, 172.700(a), 173.185(f).	To modify the special permit to authorize using a QR Code and URL that is linked to the SP can be included on the special permit package in lieu of requiring a physical copy of the special permit to travel with each shipment. (Modes 1, 2, 3).

[FR Doc. 2017–16444 Filed 8–3–17; 8:45 am]

BILLING CODE 4909–60–P

DEPARTMENT OF TRANSPORTATION

Saint Lawrence Seaway Development Corporation

Saint Lawrence Seaway Development Corporation Advisory Board—Notice of Public Meetings

AGENCY: Saint Lawrence Seaway Development Corporation (SLSDC); DOT.

ACTION: Notice of public meeting.

SUMMARY: This notice announces the public meeting via conference call of the Saint Lawrence Seaway Development Corporation Advisory Board.

DATES: The public meeting will be held on (all times Eastern):

- Monday, August 28, 2017, from 2:00 p.m.–4:00 p.m.

ADDRESSES: The meeting will be held via conference call at the SLSDC's

Policy Headquarters, 55 M Street SE., Suite 930, Washington, DC 20003.

FOR FURTHER INFORMATION CONTACT: Wayne Williams, Chief of Staff, Saint Lawrence Seaway Development Corporation, 1200 New Jersey Avenue SE., Washington, DC 20590; 202–366–0091.

SUPPLEMENTARY INFORMATION: Pursuant to Section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463; 5 U.S.C. App. I), notice is hereby given of a meeting of the Advisory Board of the Saint Lawrence Seaway Development Corporation (SLSDC). The agenda for this meeting will be as follows:

August 28, 2017, from 2:00 p.m.–4:00 p.m.

1. Opening Remarks
2. Consideration of Minutes of Past Meeting
3. Quarterly Report
4. Old and New Business
5. Closing Discussion
6. Adjournment

Public Participation

Attendance at the meeting is open to the interested public but limited to the space available. With the approval of the Administrator, members of the public may present oral statements at the meeting. Persons wishing further information should contact the person listed in the **FOR FURTHER INFORMATION CONTACT**, not later than Monday, August 21, 2017. Any member of the public may present a written statement to the Advisory Board at any time.

Issued on: July 31, 2017.

Carrie Lavigne

Chief Counsel, Saint Lawrence Seaway Development Corporation.

[FR Doc. 2017–16471 Filed 8–3–17; 8:45 am]

BILLING CODE P

DEPARTMENT OF VETERANS AFFAIRS

[OMB Control No. 2900–0212]

Agency Information Collection Activity Under OMB Review: Veterans Mortgage Life Insurance Statement

AGENCY: Veterans Benefits Administration, Department of Veterans Affairs.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act (PRA) of 1995, this notice announces that the Veterans Benefits Administration, Department of Veterans Affairs, will submit the collection of information abstracted below to the Office of Management and Budget (OMB) for review and comment. The PRA submission describes the nature of the information collection and its expected cost and burden and it includes the actual data collection instrument.

DATES: Comments must be submitted on or before September 5, 2017.

ADDRESSES: Submit written comments on the collection of information through *www.Regulations.gov*, or to Office of Information and Regulatory Affairs, Office of Management and Budget, Attn: VA Desk Officer; 725 17th St. NW., Washington, DC 20503 or sent through electronic mail to *oira_submission@omb.eop.gov.* Please refer to ''OMB Control No. 2900–0212'' in any correspondence.

FOR FURTHER INFORMATION CONTACT: Cynthia Harvey-Pryor, Enterprise Records Service (005R1B), Department of Veterans Affairs, 810 Vermont Avenue NW., Washington, DC 20420, (202) 461–5870 or email *cynthia.harvey-pryor@va.gov.* Please refer to ''OMB Control No. 2900–0212'' in any correspondence.

SUPPLEMENTARY INFORMATION:

Authority: 44 U.S.C. 3501–21.

Title: Veterans Mortgage Life Insurance Statement (VA Form 29–8636)

OMB Control Number: 2900–0212.

Type of Review: Reinstatement with change of a previously approved collection.

Abstract: VA Form 29–8636 is used by veterans who have received Specially Adapted Housing Grants to decline VMLI. The information on the form is required by law, 38 U.S.C. Section 806.

An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. The **Federal Register** Notice with a 60-day comment period soliciting comments on this collection of information was published at 82 FR 104 on June 1, 2017, pages 25499 and 25500.

Affected Public: Individuals or Households.

Estimated Annual Burden: 250 hours.

Estimated Average Burden per Respondent: 15 minutes.

Frequency of Response: On occasion.

Estimated Number of Respondents: 1,000.

By direction of the Secretary.

Cynthia Harvey-Pryor,

Department Clearance Officer, Enterprise Records Service, Office of Quality and Compliance, Department of Veterans Affairs.

[FR Doc. 2017–16408 Filed 8–3–17; 8:45 am]

BILLING CODE 8320–01–P

DEPARTMENT OF VETERANS AFFAIRS

[OMB Control No. 2900–0786]

Agency Information Collection Activity Under OMB Review: Vocational Rehabilitation and Employment (VR&E) Longitudinal Study Survey

AGENCY: Veterans Benefits Administration, Department of Veterans Affairs.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act (PRA) of 1995, this notice announces that the Veterans Benefits Administration, Department of Veterans Affairs, will submit the collection of information abstracted below to the Office of Management and Budget (OMB) for review and comment. The PRA submission describes the nature of the information collection and its expected cost and burden and it includes the actual data collection instrument.

DATES: Comments must be submitted on or before September 5, 2017.

ADDRESSES: Submit written comments on the collection of information through *www.Regulations.gov,* or to Office of Information and Regulatory Affairs, Office of Management and Budget, Attn: VA Desk Officer; 725 17th St. NW., Washington, DC 20503 or sent through electronic mail to *oira_submission@omb.eop.gov.* Please refer to ''OMB Control No. 2900–0786'' in any correspondence.

FOR FURTHER INFORMATION CONTACT: Cynthia Harvey-Pryor, Enterprise Records Service (005R1B), Department of Veterans Affairs, 810 Vermont Avenue NW., Washington, DC 20420, (202) 461–5870 or email *cynthia.harvey-pryor@va.gov.* Please refer to ''OMB Control No. 2900–0786'' in any correspondence.

SUPPLEMENTARY INFORMATION:

Authority: Public Law 110–389, Sec. 334.

Title: Vocational Rehabilitation and Employment (VR&E) Longitudinal Study Survey.

OMB Control Number: 2900–0786.

Type of Review: Extension without change of a currently approved collection.

Abstract: As part of Public Law 110–389, Vocational Rehabilitation & Employment (VR&E) VetSuccess Program is conducting a Longitudinal Study of veterans participating in VR&E. This study will take place over the next 20 years. An agency may not conduct or sponsor, and a person is not required to

respond to a collection of information unless it displays a currently valid OMB control number. The **Federal Register** Notice with a 60-day comment period soliciting comments on this collection of information was published at 82 FR 2017–11301 on June 1, 2017, page 25500.

Affected Public: Individuals or Households.

Estimated Annual Burden: 2,333.

Estimated Average Burden per Respondent: 20 minutes.

Frequency of Response: Annually over the course of 20 years.

Estimated Number of Respondents: 7,000.

By direction of the Secretary.

Cynthia Harvey-Pryor,

Department Clearance Officer, Enterprise Records Service, Office of Quality and Compliance, Department of Veterans Affairs.

[FR Doc. 2017–16407 Filed 8–3–17; 8:45 am]

BILLING CODE 8320–01–P

FEDERAL REGISTER

Vol. 82 Friday,

No. 149 August 4, 2017

Part II

Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Parts 409, 411, 413, 424, and 488

Medicare Program; Prospective Payment System and Consolidated Billing for Skilled Nursing Facilities for FY 2018, SNF Value-Based Purchasing Program, SNF Quality Reporting Program, Survey Team Composition, and Correction of the Performance Period for the NHSN HCP Influenza Vaccination Immunization Reporting Measure in the ESRD QIP for PY 2020; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 409, 411, 413, 424, and 488

[CMS–1679–F]

RIN 0938–AS96

Medicare Program; Prospective Payment System and Consolidated Billing for Skilled Nursing Facilities for FY 2018, SNF Value-Based Purchasing Program, SNF Quality Reporting Program, Survey Team Composition, and Correction of the Performance Period for the NHSN HCP Influenza Vaccination Immunization Reporting Measure in the ESRD QIP for PY 2020

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) 2018. It also revises and rebases the market basket index by updating the base year from 2010 to 2014, and by adding a new cost category for Installation, Maintenance, and Repair Services. The rule also finalizes revisions to the SNF Quality Reporting Program (QRP), including measure and standardized resident assessment data policies and policies related to public display. In addition, it finalizes policies for the Skilled Nursing Facility Value-Based Purchasing Program that will affect Medicare payment to SNFs beginning in FY 2019. The final rule also clarifies the regulatory requirements for team composition for surveys conducted for investigating a complaint and aligns regulatory provisions for investigation of complaints with the statutory requirements. The final rule also finalizes the performance period for the National Healthcare Safety Network (NHSN) Healthcare Personnel (HCP) Influenza Vaccination Reporting Measure included in the End-Stage Renal Disease (ESRD) Quality Incentive Program (QIP) for Payment Year 2020.

DATES: These regulations are effective on October 1, 2017.

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.

Michelle King, (410) 786–3667, for information related to skilled nursing facility quality reporting program.

James Poyer, (410) 786–2261, for information related to the skilled nursing facility value-based purchasing program.

Delia Houseal, (410) 786–2724, for information related to the end-stage renal disease quality incentive program.

Rebecca Ward, (410) 786–1732 and Caecilia Blondiaux, (410) 786–2190, for survey type definitions.

SUPPLEMENTARY INFORMATION:

Availability of Certain Tables Exclusively Through the Internet on the CMS Web site

As discussed in the FY 2014 SNF PPS final rule (78 FR 47936), 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.

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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
ALJ Administrative Law Judge
ARD Assessment reference date
BBA Balanced Budget Act of 1997, Public Law 105–33
BBRA Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999, Public Law 106–113
BIPA Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000, Public Law 106–554
CAH Critical access hospital
CARE Continuity Assessment Record and Evaluation
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
DTI Deep tissue injuries
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
ICD–10–CM International Classification of Diseases, 10th Revision, Clinical Modification
IGI IHS Global Inc.
IMPACT Improving Medicare Post-Acute Care Transformation Act of 2014, Public Law 113–185
IPPS Inpatient prospective payment system
IRF Inpatient Rehabilitation Facility

IRF–PAI Inpatient Rehabilitation Facility Patient Assessment Instrument
LTC Long-term care
LTCH Long-term care hospital
MACRA Medicare Access and CHIP Reauthorization Act of 2015, Public Law 114–10
MAP Measures Application Partnership
MDS Minimum data set
MFP Multifactor productivity
MMA Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Public Law 108–173
MSA Metropolitan statistical area
NF Nursing facility
NQF National Quality Forum
OASIS Outcome and Assessment Information Set
OBRA 87 Omnibus Budget Reconciliation Act of 1987, Public Law 100–203
OMB Office of Management and Budget
PAC Post-acute care
PAMA Protecting Access to Medicare Act of 2014, Public Law 113–93
PPS Prospective Payment System
PQRS Physician Quality Reporting System
QIES Quality Improvement and 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, Public Law 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
SNF Skilled nursing facility
SNF PMR Skilled Nursing Facility Payment Models Research
SNF QRP Skilled Nursing Facility Quality Reporting Program
SNF VBP Skilled Nursing Facility Value-Based Purchasing Program
SNFPPR Skilled Nursing Facility Potentially Preventable Readmission Measure
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, Public Law 104–4
VBP Value-based purchasing

I. Executive Summary

A. Purpose

This final rule updates the SNF prospective payment rates for FY 2018 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. of this final rule). This final rule also finalizes updates to the requirements for the Skilled Nursing Facility Quality Reporting Program (SNF QRP), additional policies for the Skilled Nursing Facility Value-Based Purchasing Program (SNF VBP), and clarification of requirements related to survey team composition and investigation of complaints under §§ 488.30, 488.301, 488.308, and 488.314. The final rule also finalizes one proposal related to the performance period for the National Healthcare Safety Network (NHSN) Healthcare Personnel (HCP) Influenza Vaccination Reporting Measure included in the End-Stage Renal Disease (ESRD) Quality Incentive Program (QIP).

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 2017 (81 FR 51970), which reflects the SNF market basket update, as required by section 1888(e)(5)(B)(iii) of the Act for FY 2018. Additionally, in section III.B.1. of this final rule, we are finalizing our proposal to revise and rebase the market basket index for FY 2018 and subsequent FYs by updating the base year from 2010 to 2014, and by adding a new cost category for Installation, Maintenance, and Repair Services. We are also finalizing additional polices, measures and data reporting requirements for the Skilled Nursing Facility Quality Reporting Program (SNF QRP) and requirements for the SNF VBP Program, including an exchange function to translate SNF performance scores calculated using the program's scoring methodology into value-based incentive payments.

We are also clarifying the regulatory requirements for team composition for surveys conducted for the purposes of investigating a complaint and on-site monitoring of compliance, and to align the regulatory provisions for special surveys and investigation of complaints with the statute. The changes clarify that the requirement for an interdisciplinary team that must include a registered nurse is applicable to surveys conducted under sections 1819(g)(2) and 1919(g)(2) of the Act, and not to those surveys conducted to investigate complaints or to monitor compliance on-site under sections 1819(g)(4) and 1919(g)(4) of the Act. Revising the regulatory language under §§ 488.30, 488.301, 488.308, and 488.314 to correspond to the statutory requirements found in sections 1819(g) and 1919(g) of the Act will add clarity to these requirements by making them more explicit. We are also revising the performance period for the National Healthcare Safety Network (NHSN) Healthcare Personnel (HCP) Influenza Vaccination Reporting Measure included in the End-Stage Renal Disease (ESRD) Quality Incentive Program (QIP) for PY 2020.

C. Summary of Cost and Benefits

Provision Description	Total transfers
FY 2018 SNF PPS payment rate update.	The overall economic impact of this final rule is an estimated increase of $370 million in aggregate.
FY 2018 Cost to Updating the SNF Quality Reporting Program.	The overall cost for SNFs to submit data for the SNF Quality Reporting Program for the provisions in this final rule is ($29 million).

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 physicians' 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_04152015.pdf.*

Section 215(a) of the Protecting Access to Medicare Act of 2014 (PAMA, Pub. L. 113–93, enacted on April 1, 2014) added a new section 1888(g) to the Act, which requires the Secretary to specify an all-cause all-condition hospital readmission measure and an all-condition risk-adjusted potentially preventable hospital readmission measure for the SNF setting. Additionally, section 215(b) of PAMA added a new section 1888(h) to the Act, which requires the Secretary to implement a VBP program for SNFs. Finally, section 2(a) of the Improving Medicare Post-Acute Care Transformation Act of 2014 (IMPACT Act, Pub. L. 113–185, enacted on October 6, 2014) added a new section 1899B to the Act that, among other things, requires SNFs to report standardized resident assessment data, data on quality measures, and data on resource use and other measures. In addition, section 2(c)(4) of the IMPACT Act added a new section 1888(e)(6) to the Act, which requires the Secretary to implement a quality reporting program for SNFs.

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 2017 (81 FR 51970, August 5, 2016). 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 provides the required annual updates to the per diem payment rates for SNFs for FY 2018.

III. Analysis and Responses to Public Comments on the FY 2018 SNF PPS Proposed Rule

In response to the publication of the FY 2018 SNF PPS proposed rule, we received 247 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 2018 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 requested that we instruct the Medicare Administrative Contractors to refrain from denying coverage and payment for SNF Part B claims for physiatrists visiting residents in SNFs. The commenter goes on to state their concerns regarding the potential for variability in coverage across contractors.

Response: With regard to our instructing the contractors to refrain from denying coverage or payment for SNF claims related to physiatrists visits under Part B, 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 the potential for variability among contractors, we will continue to educate the contractors to ensure compliance with all federal guidance and regulations.

Comment: One commenter requested that we consider including recreational therapy time provided to SNF residents by recreational therapists as part of the calculation of the resident's RUG–IV therapy classification or as part of determining the number of restorative nursing services provided to the resident.

Response: We appreciate the commenter raising this issue, but we do not believe there is sufficient evidence at this time regarding the efficacy of recreational therapy interventions or, more notably, data which would substantiate a determination of the effect on payment of such interventions, as such services were not considered separately, as were physical, occupational and speech-language pathology services, when RUG–IV was being developed. That being said, we would note that Medicare Part A originally paid for institutional care in various provider settings, including SNF, on a reasonable cost basis, but now makes payment using PPS methodologies, such as the SNF PPS. To the extent that one of these SNFs furnished recreational therapy to its inpatients under the previous, reasonable cost methodology, the cost of the services would have been included in the base payments when SNF PPS payment rates were derived. Under the PPS methodology, Part A makes a comprehensive payment for the bundled package of items and services that the facility furnishes during the course of a Medicare-covered stay. This package encompasses nearly all services that the beneficiary receives during the course of the stay—including any medically necessary recreational therapy—and payment for such services is included within the facility's comprehensive SNF PPS payment for the covered Part A stay itself.

B. SNF PPS Rate Setting Methodology and FY 2018 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. In the SNF PPS final rule for FY 2014 (78 FR 47939 through 47946), we revised and rebased the market basket index, which included updating the base year from FY 2004 to FY 2010. For FY 2018, as discussed in section III.D.1. of this final rule, we are rebasing and revising the SNF market basket, updating the base year from FY 2010 to 2014.

The SNF market basket index is used to compute the market basket percentage change that is used to update the SNF federal rates on an annual basis, as required by section 1888(e)(4)(E)(ii)(IV) of the Act. This market basket percentage update is adjusted by a forecast error correction, if applicable, and then further adjusted by the application of a productivity adjustment as required by section 1888(e)(5)(B)(ii) of the Act and described in section III.B.2.d. of this final rule. For FY 2018, the growth rate of the 2014-based SNF market basket is estimated to be 2.6 percent, which is based on the IHS Global Inc. (IGI) second quarter 2017 forecast with historical data through first quarter 2017.

However, we note that section 411(a) of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA, Pub. L. 114–10, enacted on April 16, 2015) amended section 1888(e) of the Act to add section 1888(e)(5)(B)(iii) of the Act. Section 1888(e)(5)(B)(iii) of the Act establishes a special rule for FY 2018 that requires the market basket percentage, after the application of the productivity adjustment, to be 1.0 percent. In accordance with section 1888(e)(5)(B)(iii) of the Act, we will use a market basket percentage of 1.0 percent to update the federal rates set forth in this final rule. In section III.B.2.e. of this final rule, we discuss the specific application of the MACRA-specified market basket adjustment to the forthcoming annual update of the SNF PPS payment rates. In addition, in section III.D.2. of this final rule, we discuss the 2 percent reduction applied to the market basket update for those SNFs that fail to submit measures data as required by section 1888(e)(6)(A) of the Act.

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. Absent the addition of section 1888(e)(5)(B)(iii) of the Act, added by section 411(a) of MACRA, we would have used the percentage change in the SNF market basket index to compute the update factor for FY 2018. Based on the revision and rebasing of the SNF market basket discussed in section III.D.1. of this final rule, this factor is based on the IGI second quarter 2017 forecast (with historical data through the first quarter 2017) of the FY 2018 percentage increase in the 2014-based SNF market basket index reflecting routine, ancillary, and capital-related expenses. As discussed in sections III.B.2.c. and III.B.2.d. of this final rule, this market basket percentage change would have been 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. As noted previously, section 1888(e)(5)(B)(iii) of the Act, added by section 411(a) of the MACRA, requires us to use a 1.0 percent market basket percentage instead of the estimated 2.6 percent market basket percentage, adjusted as described below, to adjust the SNF PPS federal rates for FY 2018. Additionally, 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 is 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 2016 (the most recently available FY for which there is final data), the estimated increase in the market basket index was 2.3 percentage points, while the actual increase for FY 2016 was 2.3 percentage points, resulting in the actual increase being the same as 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 2018 market basket percentage change of 2.6 percent would not have been adjusted to account for the forecast error correction. Table 1 shows the forecasted and actual market basket amounts for FY 2016.

TABLE 1—DIFFERENCE BETWEEN THE FORECASTED AND ACTUAL MARKET BASKET INCREASES FOR FY 2016

Index	Forecasted FY 2016 Increase *	Actual FY 2016 Increase **	FY 2016 difference
SNF	2.3	2.3	0.0

* Published in **Federal Register**; based on second quarter 2015 IGI forecast (2010-based index).
** Based on the second quarter 2017 IGI forecast, with historical data through the first quarter 2017 (2010-based index).

d. Multifactor Productivity Adjustment

Section 1888(e)(5)(B)(ii) of the Act, as added by section 3401(b) of the Patient Protection and Affordable Care Act (Affordable Care Act, Pub. L. 111–148, enacted on March 23, 2010) requires that, in FY 2012 and in subsequent FYs, the market basket percentage under the SNF PPS (as described in section 1888(e)(5)(B)(i) of the Act) is to be reduced annually by the multifactor productivity (MFP) adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act. Section 1886(b)(3)(B)(xi)(II) of the Act, in turn, defines the MFP 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 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.*

(1) 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) of the Act (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 being less than such payment rates for the preceding fiscal year.

If not for the enactment of section 411(a) of the MACRA, the FY 2018 update would include a calculation of the MFP adjustment as the 10-year moving average of changes in MFP for the period ending September 30, 2018, which is estimated to be 0.6 percent. Also, if not for the enactment of section 411(a) of the MACRA, consistent with section 1888(e)(5)(B)(i) of the Act and § 413.337(d)(2), the market basket percentage for FY 2018 for the SNF PPS would be based on IGI's second quarter 2017 forecast of the SNF market basket update, which is estimated to be 2.6 percent. 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 would then be reduced by the MFP adjustment (the 10-year moving average of changes in MFP for the period ending September 30, 2018) of 0.6 percent, which would be calculated as described above and based on IGI's second quarter 2017 forecast. Absent the enactment of section 411(a) of MACRA, the resulting MFP-adjusted SNF market basket update would have been equal to 2.0 percent, or 2.6 percent less 0.6 percentage point. However, as discussed above, section 1888(e)(5)(B)(iii) of the Act, added by section 411(a) of the MACRA, requires us to apply a 1.0 percent positive market basket adjustment in determining the FY 2018 SNF payment rates set forth in this final rule, without regard to the market basket update as adjusted by the MFP adjustment described above.

e. Market Basket Update Factor for FY 2018

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 2018 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, 2016, through September 30, 2017 to the average market basket level for the period of October 1, 2017, through September 30, 2018. This process yields a percentage change in the 2014-based SNF market basket of 2.6 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 2016 SNF market basket percentage change and the actual FY 2016 SNF market basket percentage change (FY 2016 is the most recently available FY for which there is historical data) did not exceed the 0.5 percentage point threshold, the FY 2018 market basket percentage change of 2.6 percent would not have been adjusted by the forecast error correction.

If not for the enactment of section 411(a) of the MACRA, the SNF market basket for FY 2018 would be determined in accordance with section 1888(e)(5)(B)(ii) of the Act, which 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, 2018) of 0.6 percent, as described in section III.B.2.d. of this final rule. Thus, absent the enactment of MACRA, the resulting net SNF market basket update would equal 2.0 percent, or 2.6 percent less the 0.6 percentage point MFP adjustment. We note that our policy has been that, if more recent data become available (for example, a more recent estimate of the SNF market basket and/or MFP adjustment), we would use such data, if appropriate, to determine the SNF market basket percentage change, labor-related share relative importance, forecast error adjustment, and MFP adjustment in the SNF PPS final rule.

Commenters submitted the following comments related to the proposed rule's discussion of the market basket update factor for FY 2018. A discussion of these comments, along with our responses, appears below.

Comment: We received a number of comments in relation to applying the FY 2018 market basket update factor in the determination of the FY 2018 unadjusted federal per diem rates, with some commenters supporting its application in determining the FY 2018 unadjusted per diem rates, while others opposed its application. In their March 2017 report (available at *http://medpac.gov/docs/default-source/reports/mar17_medpac_ch8.pdf*) and in their comment on the FY 2018 SNF PPS proposed rule, MedPAC recommended that we eliminate the market basket update for SNFs altogether for FY 2018 and FY 2019 and implement revisions to the SNF PPS. A few commenters also encouraged us to consider the ''gap'' between the customary market basket update, as reflected in the MFP-adjusted market basket update factor described above and the MACRA-required 1.0 percentage point market basket update.

Response: We appreciate all of the comments received on the proposed market basket update for FY 2018. In response to those comments opposing the application of the FY 2018 market basket update factor in determining the FY 2018 unadjusted federal per diem rates (specifically, MedPAC's proposal to eliminate the market basket update for SNFs), we note that under sections 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, and that, under section 1888(e)(5)(B)(iii) of the Act (as added by section 411(a) of MACRA), for FY 2018, that update must be 1.0 percentage point.

With regard to those comments on the ''gap'' between the standard market basket update and the MACRA-required update, we appreciate these commenters' concerns, but we are required in section 1888(e)(5)(B)(iii) of the Act, as added by section 411(a) of MACRA, to apply the 1.0 percentage point update factor for FY 2018.

Comment: One commenter requested that we engage in an ongoing dialogue with the commenter's association on their market basket research, which would serve to inform us and support any analogous CMS reform efforts.

Response: We appreciate the commenter's review of the market basket and interest in continued dialogue regarding their research. The commenter is encouraged to submit any research to *CMSDNHS@cms.hhs.gov.*

Comment: One commenter stated that we have the statutory authority to implement geographically-specific updates associated with state and/or regional minimum wage laws. The commenter requested that such updates be made at the Core-Based Statistical Area (CBSA) levels.

Response: We would note that any increases in wages resulting from state and/or regional minimum wage laws are likely to be reflected in data used to create the SNF PPS wage index. Therefore, we believe such standards are already taken into account in the calculation of the SNF PPS wage index to the extent that these laws have an impact on wages.

Accordingly, after considering the comments received, for the reasons specified in this final rule and in the FY 2018 SNF PPS proposed rule (82 FR 21017 through 21019), we are finalizing the FY 2018 market basket factor of 1.0 percent, as required by section 411(a) of MACRA. Historically, we have used the SNF market basket, adjusted as described above, to adjust each per diem component of the federal rates forward to reflect the change in the average prices from one year to the next. However, section 1888(e)(5)(B)(iii) of the Act, as added by section 411(a) of the MACRA, requires us to use a market basket percentage of 1.0 percent, after application of the MFP adjustment to adjust the federal rates for FY 2018. Under section 1888(e)(5)(B)(iii) of the Act, the market basket percentage increase used to determine the federal rates set forth in this final rule will be 1.0 percent for FY 2018. Tables 2 and 3 reflect the updated components of the unadjusted federal rates for FY 2018, prior to adjustment for case-mix.

TABLE 2—FY 2018 UNADJUSTED FEDERAL RATE PER DIEM URBAN

Rate component	Nursing—case-mix	Therapy—case-mix	Therapy—non-case-mix	Non-case-mix
Per Diem Amount	$177.26	$133.52	$17.59	$90.47

TABLE 3—FY 2018 UNADJUSTED FEDERAL RATE PER DIEM RURAL

Rate component	Nursing—case-mix	Therapy—case-mix	Therapy—non-case-mix	Non-case-mix
Per Diem Amount	$169.34	$153.96	$18.79	$92.14

In addition, we note that section 1888(e)(6)(A)(i) of the Act provides that, beginning in FY 2018, SNFs that fail to submit data, as applicable, in accordance with sections 1888(e)(6)(B)(i)(II) and (III) of the Act for a fiscal year will receive a 2.0 percentage point reduction to their market basket update for the fiscal year involved, after application of section 1888(e)(5)(B)(ii) of the Act (the MFP adjustment) and section 1888(e)(5)(B)(iii) of the Act (the 1 percent market basket increase for FY 2018) (for additional information on the SNF QRP, including the statutory authority and the selected measures, we refer readers to section III.D.2. of this final rule). In addition, section 1888(e)(6)(A)(ii) of the Act states that application of the 2.0 percentage point reduction (after application of section 1888(e)(5)(B)(ii) and (iii) of the Act) may result in the market basket index

percentage change being less than 0.0 for a fiscal year, and may result in payment rates for a fiscal year being less than such payment rates for the preceding fiscal year. Section 1888(e)(6)(A)(iii) of the Act further specifies that the 2.0 percentage point reduction is applied in a noncumulative manner, so that any reduction made under section 1888(e)(6)(A)(i) of the Act shall apply only for the fiscal year involved, and the Secretary shall not take into account such reduction in computing the payment amount for a subsequent fiscal year. We did not receive any comments specifically on the market basket reduction under the SNF QRP and any comments on the SNF QRP more broadly are discussed in section III.D.2 of this final rule.

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 through 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 III.C.1. of this final rule, 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 Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA, Pub. L. 108–173, enacted December 8, 2003) 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 only 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 time being.

For the limited number of SNF residents that qualify for this add-on, there is a significant increase in payments. For example, using FY 2015 data (which still used ICD–9–CM coding), we identified fewer than 5085 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 2018, an urban facility with a resident with AIDS in RUG–IV group ''HC2'' would have a case-mix adjusted per diem payment of $443.08 (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 $1,010.22.

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 FY 2018 payment rates set forth in this final rule reflect the use of the RUG–IV case-mix classification system from October 1, 2017, through September 30, 2018. We list the case-mix adjusted RUG–IV payment rates for FY 2018, 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 applies 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).

TABLE 4—RUG–IV CASE-MIX ADJUSTED FEDERAL RATES AND ASSOCIATED INDEXES—URBAN

RUG–IVcategory	Nursing index	Therapy index	Nursing component	Therapy component	Non-case mix therapy comp	Non-case mix component	Total rate
RUX	$2.67	$1.87	$473.28	$249.68	.....	$90.47	$813.43
RUL	2.57	1.87	455.56	249.68	.....	90.47	795.71
RVX	2.61	1.28	462.65	170.91	.....	90.47	724.03
RVL	2.19	1.28	388.20	170.91	.....	90.47	649.58
RHX	2.55	0.85	452.01	113.49	.....	90.47	655.97
RHL	2.15	0.85	381.11	113.49	.....	90.47	585.07
RMX	2.47	0.55	437.83	73.44	.....	90.47	601.74
RML	2.19	0.55	388.20	73.44	.....	90.47	552.11
RLX	2.26	0.28	400.61	37.39	.....	90.47	528.47
RUC	1.56	1.87	276.53	249.68	.....	90.47	616.68
RUB	1.56	1.87	276.53	249.68	.....	90.47	616.68
RUA	0.99	1.87	175.49	249.68	.....	90.47	515.64
RVC	1.51	1.28	267.66	170.91	.....	90.47	529.04
RVB	1.11	1.28	196.76	170.91	.....	90.47	458.14
RVA	1.10	1.28	194.99	170.91	.....	90.47	456.37
RHC	1.45	0.85	257.03	113.49	.....	90.47	460.99
RHB	1.19	0.85	210.94	113.49	.....	90.47	414.90
RHA	0.91	0.85	161.31	113.49	.....	90.47	365.27
RMC	1.36	0.55	241.07	73.44	.....	90.47	404.98
RMB	1.22	0.55	216.26	73.44	.....	90.47	380.17
RMA	0.84	0.55	148.90	73.44	.....	90.47	312.81
RLB	1.50	0.28	265.89	37.39	.....	90.47	393.75
RLA	0.71	0.28	125.85	37.39	.....	90.47	253.71
ES3	3.58	.....	634.59	.....	$17.59	90.47	742.65
ES2	2.67	.....	473.28	.....	17.59	90.47	581.34
ES1	2.32	.....	411.24	.....	17.59	90.47	519.30
HE2	2.22	.....	393.52	.....	17.59	90.47	501.58
HE1	1.74	.....	308.43	.....	17.59	90.47	416.49
HD2	2.04	.....	361.61	.....	17.59	90.47	469.67
HD1	1.60	.....	283.62	.....	17.59	90.47	391.68
HC2	1.89	.....	335.02	.....	17.59	90.47	443.08
HC1	1.48	.....	262.34	.....	17.59	90.47	370.40
HB2	1.86	.....	329.70	.....	17.59	90.47	437.76
HB1	1.46	.....	258.80	.....	17.59	90.47	366.86
LE2	1.96	.....	347.43	.....	17.59	90.47	455.49
LE1	1.54	.....	272.98	.....	17.59	90.47	381.04
LD2	1.86	.....	329.70	.....	17.59	90.47	437.76
LD1	1.46	.....	258.80	.....	17.59	90.47	366.86
LC2	1.56	.....	276.53	.....	17.59	90.47	384.59
LC1	1.22	.....	216.26	.....	17.59	90.47	324.32
LB2	1.45	.....	257.03	.....	17.59	90.47	365.09
LB1	1.14	.....	202.08	.....	17.59	90.47	310.14
CE2	1.68	.....	297.80	.....	17.59	90.47	405.86
CE1	1.50	.....	265.89	.....	17.59	90.47	373.95
CD2	1.56	.....	276.53	.....	17.59	90.47	384.59
CD1	1.38	.....	244.62	.....	17.59	90.47	352.68
CC2	1.29	.....	228.67	.....	17.59	90.47	336.73
CC1	1.15	.....	203.85	.....	17.59	90.47	311.91
CB2	1.15	.....	203.85	.....	17.59	90.47	311.91
CB1	1.02	.....	180.81	.....	17.59	90.47	288.87
CA2	0.88	.....	155.99	.....	17.59	90.47	264.05
CA1	0.78	.....	138.26	.....	17.59	90.47	246.32
BB2	0.97	.....	171.94	.....	17.59	90.47	280.00
BB1	0.90	.....	159.53	.....	17.59	90.47	267.59
BA2	0.70	.....	124.08	.....	17.59	90.47	232.14
BA1	0.64	.....	113.45	.....	17.59	90.47	221.51
PE2	1.50	.....	265.89	.....	17.59	90.47	373.95
PE1	1.40	.....	248.16	.....	17.59	90.47	356.22
PD2	1.38	.....	244.62	.....	17.59	90.47	352.68
PD1	1.28	.....	226.89	.....	17.59	90.47	334.95
PC2	1.10	.....	194.99	.....	17.59	90.47	303.05
PC1	1.02	.....	180.81	.....	17.59	90.47	288.87
PB2	0.84	.....	148.90	.....	17.59	90.47	256.96
PB1	0.78	.....	138.26	.....	17.59	90.47	246.32
PA2	0.59	.....	104.58	.....	17.59	90.47	212.64
PA1	0.54	.....	95.72	.....	17.59	90.47	203.78

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	$452.14	$287.91	.....	$92.14	$832.19
RUL	2.57	1.87	435.20	287.91	.....	92.14	815.25
RVX	2.61	1.28	441.98	197.07	.....	92.14	731.19
RVL	2.19	1.28	370.85	197.07	.....	92.14	660.06
RHX	2.55	0.85	431.82	130.87	.....	92.14	654.83
RHL	2.15	0.85	364.08	130.87	.....	92.14	587.09
RMX	2.47	0.55	418.27	84.68	.....	92.14	595.09
RML	2.19	0.55	370.85	84.68	.....	92.14	547.67
RLX	2.26	0.28	382.71	43.11	.....	92.14	517.96
RUC	1.56	1.87	264.17	287.91	.....	92.14	644.22
RUB	1.56	1.87	264.17	287.91	.....	92.14	644.22
RUA	0.99	1.87	167.65	287.91	.....	92.14	547.70
RVC	1.51	1.28	255.70	197.07	.....	92.14	544.91
RVB	1.11	1.28	187.97	197.07	.....	92.14	477.18
RVA	1.10	1.28	186.27	197.07	.....	92.14	475.48
RHC	1.45	0.85	245.54	130.87	.....	92.14	468.55
RHB	1.19	0.85	201.51	130.87	.....	92.14	424.52
RHA	0.91	0.85	154.10	130.87	.....	92.14	377.11
RMC	1.36	0.55	230.30	84.68	.....	92.14	407.12
RMB	1.22	0.55	206.59	84.68	.....	92.14	383.41
RMA	0.84	0.55	142.25	84.68	.....	92.14	319.07
RLB	1.50	0.28	254.01	43.11	.....	92.14	389.26
RLA	0.71	0.28	120.23	43.11	.....	92.14	255.48
ES3	3.58	.....	606.24	.....	18.79	92.14	717.17
ES2	2.67	.....	452.14	.....	18.79	92.14	563.07
ES1	2.32	.....	392.87	.....	18.79	92.14	503.80
HE2	2.22	.....	375.93	.....	18.79	92.14	486.86
HE1	1.74	.....	294.65	.....	18.79	92.14	405.58
HD2	2.04	.....	345.45	.....	18.79	92.14	456.38
HD1	1.60	.....	270.94	.....	18.79	92.14	381.87
HC2	1.89	.....	320.05	.....	18.79	92.14	430.98
HC1	1.48	.....	250.62	.....	18.79	92.14	361.55
HB2	1.86	.....	314.97	.....	18.79	92.14	425.90
HB1	1.46	.....	247.24	.....	18.79	92.14	358.17
LE2	1.96	.....	331.91	.....	18.79	92.14	442.84
LE1	1.54	.....	260.78	.....	18.79	92.14	371.71
LD2	1.86	.....	314.97	.....	18.79	92.14	425.90
LD1	1.46	.....	247.24	.....	18.79	92.14	358.17
LC2	1.56	.....	264.17	.....	18.79	92.14	375.10
LC1	1.22	.....	206.59	.....	18.79	92.14	317.52
LB2	1.45	.....	245.54	.....	18.79	92.14	356.47
LB1	1.14	.....	193.05	.....	18.79	92.14	303.98
CE2	1.68	.....	284.49	.....	18.79	92.14	395.42
CE1	1.50	.....	254.01	.....	18.79	92.14	364.94
CD2	1.56	.....	264.17	.....	18.79	92.14	375.10
CD1	1.38	.....	233.69	.....	18.79	92.14	344.62
CC2	1.29	.....	218.45	.....	18.79	92.14	329.38
CC1	1.15	.....	194.74	.....	18.79	92.14	305.67
CB2	1.15	.....	194.74	.....	18.79	92.14	305.67
CB1	1.02	.....	172.73	.....	18.79	92.14	283.66
CA2	0.88	.....	149.02	.....	18.79	92.14	259.95
CA1	0.78	.....	132.09	.....	18.79	92.14	243.02
BB2	0.97	.....	164.26	.....	18.79	92.14	275.19
BB1	0.90	.....	152.41	.....	18.79	92.14	263.34
BA2	0.70	.....	118.54	.....	18.79	92.14	229.47
BA1	0.64	.....	108.38	.....	18.79	92.14	219.31
PE2	1.50	.....	254.01	.....	18.79	92.14	364.94
PE1	1.40	.....	237.08	.....	18.79	92.14	348.01
PD2	1.38	.....	233.69	.....	18.79	92.14	344.62
PD1	1.28	.....	216.76	.....	18.79	92.14	327.69
PC2	1.10	.....	186.27	.....	18.79	92.14	297.20
PC1	1.02	.....	172.73	.....	18.79	92.14	283.66
PB2	0.84	.....	142.25	.....	18.79	92.14	253.18
PB1	0.78	.....	132.09	.....	18.79	92.14	243.02
PA2	0.59	.....	99.91	.....	18.79	92.14	210.84
PA1	0.54	.....	91.44	.....	18.79	92.14	202.37

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 2018, 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 2018, the updated wage data are for hospital cost reporting periods beginning on or after October 1, 2013 and before October 1, 2014 (FY 2014 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. More specifically, we believe auditing all SNF cost reports, similar to the process used to audit inpatient hospital cost reports for purposes of the Inpatient Prospective Payment System (IPPS) wage index, would place a burden on providers in terms of responding to documented audit requests. We also believe that adopting such an approach would require a significant commitment of resources by CMS and the Medicare Administrative Contractors, potentially far in excess of those required under the IPPS given that there are nearly five times as many SNFs as there are hospitals. Therefore, while we continue to believe that the development of such an audit process could improve SNF cost reports in such a manner as to permit us to establish a SNF-specific wage index, we do not regard an undertaking of this magnitude as being feasible within the current level of programmatic resources.

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 2018 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 stated in the proposed rule we would use the average wage index from all contiguous Core-Based Statistical Areas (CBSAs) as a reasonable proxy. For FY 2018, there are no rural geographic areas that do not have hospitals, and thus, we stated that this methodology would not be applied. For rural Puerto Rico, we stated that 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 stated 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 stated 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 2018, the only urban area without wage index data available is CBSA 25980, Hinesville-Fort Stewart, GA. The wage index applicable to FY 2018 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.*

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 *https://www.whitehouse.gov/omb/bulletins_b03-04,* 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 one-year transition on September 30, 2006, we have used the full CBSA-based wage index values.

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 on June 28, 2010 in the **Federal Register** (75 FR 37246 through 37252). Subsequently, 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. 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 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 above, the wage index applicable to FY 2018 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 stated in the proposed rule 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; Professional fees: Labor-related; Administrative and Facilities Support Services; All other—Labor-Related Services; and a proportion of Capital-Related expenses. Effective beginning FY 2018, as discussed in section III.D.1. of the proposed rule, we proposed to revise the labor-related share to reflect the relative importance of the 2014-based SNF market basket cost weights for the following cost categories: Wages and Salaries; Employee Benefits; Professional fees: Labor-related; Administrative and Facilities Support services; Installation, Maintenance, and Repair 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 2018. 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 2018 than the base year weights from the SNF market basket. The methodology for calculating the labor-related portion for FY 2018 is discussed in section III.D.1. of this final rule and the labor-related share is provided in Table 15.

We invited public comments on these proposals. A discussion of the comments we received, along with our responses, appear below.

Comment: One commenter expressed concern with what appears to be a precipitous drop in the New Bern, North Carolina (CBSA 35100) wage index. The commenter noted that in the SNF PPS final rule for 2017, the wage index for this CBSA was 0.8539, but that in the FY 2018 SNF PPS proposed rule, this value had dropped to 0.5988. The commenter requests that the information used to determine the wage indexes be reviewed prior to the release of the final rule.

Response: We appreciate the commenter's concern regarding the decrease in the wage index for CBSA 35100. There is a wage data verification and correction process which is discussed in the Inpatient Prospective Payment System (IPPS) proposed and final rules each year. The most recent discussion appears in the FY 2018 IPPS proposed rule (82 FR 19899 through 19900. 19911 through 19915). Based on the final wage data for FY 2018, the wage index for CBSA 35100 has been updated to 0.8277, which is only a slight decrease compared to the FY 2017 value.

Comment: Several commenters recommend that we continue exploring potential approaches to establish a SNF-specific wage index either by modifying the use of current hospital wage data by eliminating certain job categories specific to hospitals only, or by utilizing collected SNF-specific wage data only. More specifically, these commenters suggest that a SNF-specific wage index could benefit from weighting it by occupational mix data for SNFs, allowing for a rural floor policy, and by implementation of a reclassification system.

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 the preceding discussion in this final rule as well as our previous responses to these recurring comments (most recently published in the FY 2017 SNF PPS final rule (81 FR 51979 through 51980)), 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. As discussed above, we believe auditing all SNF cost reports, similar to the process used to audit inpatient hospital cost reports for purposes of the Inpatient Prospective Payment System (IPPS) wage index, would place a burden on providers in terms of recordkeeping and completion of the cost report worksheet. We also believe that adopting such an approach would require a significant commitment of resources by CMS and the Medicare Administrative Contractors, potentially far in excess of those required under the IPPS given that there are nearly five times as many SNFs as there are hospitals. 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.

Further, 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 by eliminating certain job categories specific to hospitals only. 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.

We note that section 315 of BIPA authorized us to establish a geographic reclassification procedure that is specific to SNFs, only after collecting the data necessary to establish a SNF-specific wage index that is based on data from nursing homes. However, to date this has been infeasible 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. To the extent we are able to develop and implement a SNF-specific wage index in the future, we may consider at that time whether it would be appropriate to implement a reclassification system and an occupational mix adjustment, as suggested by commenters.

As it relates to the suggestion that we adopt a rural floor policy with a SNF-specific wage index, we do not believe it would be prudent 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/docs/default-source/reports/mar13_ch03.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.'') As we stated in the FY 2016 SNF PPS final

rule, if we were to adopt the rural floor under the SNF PPS, we believe that the SNF PPS wage index could become vulnerable to problems similar to those that MedPAC identified in its March 2013 Report to Congress.

Accordingly, after considering the comments received and for the reasons discussed previously in this section and in the FY 2018 SNF PPS proposed rule (82 FR 21022 through 21026), we are finalizing the FY 2018 wage index adjustment and related policies as proposed in the FY 2018 SNF PPS proposed rule. For FY 2018, the updated wage data are for hospital cost reporting periods beginning on or after October 1, 2013 and before October 1, 2014 (FY 2014 cost report data). As noted above, the wage index applicable to FY 2018 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.* Tables 6 and 7 show the RUG–IV case-mix adjusted federal rates for FY 2018 by labor-related and non-labor-related components.

TABLE 6—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	$813.43	$575.91	$237.52
RUL	795.71	563.36	232.35
RVX	724.03	512.61	211.42
RVL	649.58	459.90	189.68
RHX	655.97	464.43	191.54
RHL	585.07	414.23	170.84
RMX	601.74	426.03	175.71
RML	552.11	390.89	161.22
RLX	528.47	374.16	154.31
RUC	616.68	436.61	180.07
RUB	616.68	436.61	180.07
RUA	515.64	365.07	150.57
RVC	529.04	374.56	154.48
RVB	458.14	324.36	133.78
RVA	456.37	323.11	133.26
RHC	460.99	326.38	134.61
RHB	414.90	293.75	121.15
RHA	365.27	258.61	106.66
RMC	404.98	286.73	118.25
RMB	380.17	269.16	111.01
RMA	312.81	221.47	91.34
RLB	393.75	278.78	114.98
RLA	253.71	179.63	74.08
ES3	742.65	525.80	216.85
ES2	581.34	411.59	169.75
ES1	519.30	367.66	151.64
HE2	501.58	355.12	146.46
HE1	416.49	294.87	121.62
HD2	469.67	332.53	137.14
HD1	391.68	277.31	114.37
HC2	443.08	313.70	129.38
HC1	370.40	262.24	108.16
HB2	437.76	309.93	127.83
HB1	366.86	259.74	107.12
LE2	455.49	322.49	133.00
LE1	381.04	269.78	111.26
LD2	437.76	309.93	127.83
LD1	366.86	259.74	107.12
LC2	384.59	272.29	112.30
LC1	324.32	229.62	94.70
LB2	365.09	258.48	106.61
LB1	310.14	219.58	90.56
CE2	405.86	287.35	118.51
CE1	373.95	264.76	109.19
CD2	384.59	272.29	112.30
CD1	352.68	249.70	102.98
CC2	336.73	238.40	98.33
CC1	311.91	220.83	91.08
CB2	311.91	220.83	91.08
CB1	288.87	204.52	84.35
CA2	264.05	186.95	77.10
CA1	246.32	174.39	71.93
BB2	280.00	198.24	81.76
BB1	267.59	189.45	78.14
BA2	232.14	164.36	67.78
BA1	221.51	156.83	64.68
PE2	373.95	264.76	109.19
PE1	356.22	252.20	104.02
PD2	352.68	249.70	102.98

TABLE 6—RUG–IV CASE-MIX ADJUSTED FEDERAL RATES FOR URBAN SNFS BY LABOR AND NON-LABOR COMPONENT—Continued

RUG–IV category	Total rate	Labor portion	Non-labor portion
PD1	334.95	237.14	97.81
PC2	303.05	214.56	88.49
PC1	288.87	204.52	84.35
PB2	256.96	181.93	75.03
PB1	246.32	174.39	71.93
PA2	212.64	150.55	62.09
PA1	203.78	144.28	59.50

TABLE 7—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	$832.19	$589.19	$243.00
RUL	815.25	577.20	238.05
RVX	731.19	517.68	213.51
RVL	660.06	467.32	192.74
RHX	654.83	463.62	191.21
RHL	587.09	415.66	171.43
RMX	595.09	421.32	173.77
RML	547.67	387.75	159.92
RLX	517.96	366.72	151.24
RUC	644.22	456.11	188.11
RUB	644.22	456.11	188.11
RUA	547.70	387.77	159.93
RVC	544.91	385.80	159.11
RVB	477.18	337.84	139.34
RVA	475.48	336.64	138.84
RHC	468.55	331.73	136.82
RHB	424.52	300.56	123.96
RHA	377.11	266.99	110.12
RMC	407.12	288.24	118.88
RMB	383.41	271.45	111.96
RMA	319.07	225.90	93.17
RLB	389.26	275.60	113.66
RLA	255.48	180.88	74.60
ES3	717.17	507.76	209.41
ES2	563.07	398.65	164.42
ES1	503.80	356.69	147.11
HE2	486.86	344.70	142.16
HE1	405.58	287.15	118.43
HD2	456.38	323.12	133.26
HD1	381.87	270.36	111.51
HC2	430.98	305.13	125.85
HC1	361.55	255.98	105.57
HB2	425.90	301.54	124.36
HB1	358.17	253.58	104.59
LE2	442.84	313.53	129.31
LE1	371.71	263.17	108.54
LD2	425.90	301.54	124.36
LD1	358.17	253.58	104.59
LC2	375.10	265.57	109.53
LC1	317.52	224.80	92.72
LB2	356.47	252.38	104.09
LB1	303.98	215.22	88.76
CE2	395.42	279.96	115.46
CE1	364.94	258.38	106.56
CD2	375.10	265.57	109.53
CD1	344.62	243.99	100.63
CC2	329.38	233.20	96.18
CC1	305.67	216.41	89.26
CB2	305.67	216.41	89.26
CB1	283.66	200.83	82.83
CA2	259.95	184.04	75.91
CA1	243.02	172.06	70.96
BB2	275.19	194.83	80.36
BB1	263.34	186.44	76.90
BA2	229.47	162.46	67.01
BA1	219.31	155.27	64.04

TABLE 7—RUG–IV CASE-MIX ADJUSTED FEDERAL RATES FOR RURAL SNFS BY LABOR AND NON-LABOR COMPONENT—Continued

RUG–IV category	Total rate	Labor portion	Non-labor portion
PE2	364.94	258.38	106.56
PE1	348.01	246.39	101.62
PD2	344.62	243.99	100.63
PD1	327.69	232.00	95.69
PC2	297.20	210.42	86.78
PC1	283.66	200.83	82.83
PB2	253.18	179.25	73.93
PB1	243.02	172.06	70.96
PA2	210.84	149.27	61.57
PA1	202.37	143.28	59.09

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 2018 (federal rates effective October 1, 2017), we stated in the proposed rule that we would apply an adjustment to fulfill the budget neutrality requirement. We stated we would 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 2017 to the weighted average wage adjustment factor for FY 2018. For this calculation, we stated we would use the same FY 2016 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. We proposed a budget neutrality factor of 1.0003. We did not receive any comments regarding our proposed budget neutrality calculation. Thus, we are finalizing the budget neutrality methodology as proposed. The final budget neutrality factor for FY 2018 is 1.0013. We note that this is different from the budget neutrality factor provided in the FY 2018 SNF PPS proposed rule (82 FR 21026) due to an updated wage index file and updated claims file used to calculate the budget neutrality factor.

5. Adjusted Rate Computation Example

Using the hypothetical SNF XYZ, Table 8 shows the adjustments made to the federal per diem rates to compute the provider's actual per diem PPS payment for FY 2018. We derive the Labor and Non-labor columns from Table 6. The wage index used in this example is based on the FY 2018 SNF PPS wage index, which may be found in Table A available on the CMS Web site at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/SNFPPS/WageIndex.html.* As illustrated in Table 8, SNF XYZ's total PPS payment for FY 2018 would equal $47,596.42.

TABLE 8—ADJUSTED RATE COMPUTATION EXAMPLE SNF XYZ: LOCATED IN FREDERICK, MD (URBAN CBSA 43524) WAGE INDEX: 0.9863

[See Wage Index in Table A] [1]

RUG–IVgroup	Labor	Wage index	Adjusted labor	Non-labor	Adjusted rate	Percent adjustment	Medicare days	Payment
RVX	$512.61	0.9863	$505.59	$211.42	$717.01	$717.01	14	$10,038.14
ES2	411.59	0.9863	405.95	169.75	575.70	575.70	30	17,271.00
RHA	258.61	0.9863	255.07	106.66	361.73	361.73	16	5,787.68
CC2 *	238.40	0.9863	235.13	98.33	333.46	760.29	10	7,602.90
BA2	164.36	0.9863	162.11	67.78	229.89	229.89	30	6,896.70
							100	47,596.42

* 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 § 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.

In connection with the administrative level of care presumption, in the FY 2018 SNF PPS proposed rule (82 FR 21027), we proposed to amend the existing regulations text at § 413.345 by removing the parenthetical phrase ''(including the designation of those specific Resource Utilization Groups under the resident classification system that represent the required SNF level of care, as provided in § 409.30 of this chapter)'' that currently appears in the second sentence of § 413.345. We stated in the proposed rule that the deletion of the current reference to publishing such material annually in the **Federal Register**, along with the specific reference to ''Resource Utilization Groups,'' would serve to conform the text of these regulations more closely to that of the corresponding statutory language at section 1888(e)(4)(H)(ii) of the Act, which refers in more general terms to the applicable ''case mix classification system.'' Moreover, we noted in the proposed rule that the recurring announcements in the **Federal Register** of the administrative presumption's designated groups as part of each annual update of the SNF PPS rates has in actual practice proven to be largely a formality, resulting in exactly the same designated groups repetitively being promulgated routinely year after year. Accordingly, we proposed instead to disseminate this standard description of the administrative presumption's designated groups exclusively through the SNF PPS Web site, and to announce such designations in rulemaking only in the event that we are actually proposing to make changes in them.

Along with this proposed revision, we also proposed to make appropriate conforming revisions in other portions of the regulations text (82 FR 21027). Specifically, we proposed to remove from the introductory text of § 409.30, the parenthetical phrase ''(in the annual publication of Federal prospective payment rates described in § 413.345 of this chapter)'' for the same reasons we proposed to remove the parenthetical phrase from § 413.345, as discussed in the proposed rule and in this final rule above. In addition, we proposed to replace the phrase to ''one of the Resource Utilization Groups that is designated'' in § 409.30's introductory text with the phrase ''one of the case-mix classifiers CMS designates'' to conform more closely with the statutory language in section 1888(e)(4)(G) and (H) of the Act, which refers in more general terms to the ''resident classification system'' or ''case mix classification system,'' and to clarify that ''CMS'' makes these designations. Additionally, we proposed to revise § 409.30 to reflect more clearly our longstanding policy that the assignment of a designated case-mix classifier would serve to trigger the administrative presumption only when that assignment is itself correct. As we noted in the FY 2000 SNF PPS final rule (64 FR 41667, July 30, 1999), ''. . . 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.'' We also proposed to make similar conforming revisions in the ''resident classification system'' definition that currently appears in § 413.333 to replace ''Resource Utilization Groups'' with ''resident classification system'', as well as in the material in § 424.20(a)(1)(ii) on SNF level of care certifications to replace the phrase ''one of the Resource Utilization Groups designated'' with ''one of the case-mix classifiers that CMS designates,'' in both cases to conform more closely with the statutory language in section 1888(e)(4)(G) and (H) of the Act, as discussed in the proposed rule (82 FR 21027) and in this final rule, which refers in more general terms to the ''resident classification system'' or ''case mix classification system,'' and to clarify in § 424.20(a)(1)(ii) that ''CMS'' designates these case-mix classifiers. Finally, regarding § 424.20, we proposed to revise paragraph (e)(2)(ii)(B)(*2*) by updating its existing cross-reference to the provision at § 483.40(e) on delegating physician tasks in SNFs, which was recently redesignated as new § 483.30(e) under the revised long-term care facility requirements for participation (81 FR 68861, October 4, 2016). Finally, we proposed to remove the word ''Optional'' from the title of 42 CFR part 413 (82 FR 21098), as this is an obsolete reference to an optional prospective payment methodology for low-volume SNFs that predated the SNF PPS and is no longer in effect.

Commenters submitted the following comments on our proposals described above related to the SNF Level of Care—Administrative Presumption aspects of the SNF PPS. A discussion of these comments, along with our responses, appears below.

Comment: We received a comment about our proposed revisions to §§ 413.333 and 413.345 that would result in removing the term ''Resource Utilization Groups,'' and in § 413.333, utilizing the term ''resident

classification system'' in its place. The commenter interpreted our use of the term ''resident classification system'' in this context as referring specifically to the Resident Classification System, Version I (RCS–I), the particular case-mix classification model that is currently under development as discussed in our advance notice of proposed rulemaking with comment (CMS–1686–ANPRM, 82 FR 20980, May 4, 2017). Based on that assumption, the commenter expressed the view that it would be premature and confusing to adopt terminology referencing a particular model that has not been finalized at this point.

Response: We wish to clarify that our use of the term ''resident classification system'' in this context refers solely to a case-mix classification system in the generic sense, and not to the particular model discussed in the ANPRM, which we will continue to refer to as the Resident Classification System, Version I (or RCS–I). We note that the term ''resident classification system'' in the more generic sense has long been utilized as such in the existing regulations at § 413.333, and that our proposed changes were not intended to restrict the regulations text to any one particular type of classification system, but rather, to do the opposite by removing the existing, specific references to the RUG model. As we noted in the proposed rule (82 FR 21027), such revisions would actually serve to conform the regulations text ''. . . more closely with the statutory language in section 1888(e)(4)(G) and (H) of the Act, . . . which refers *in more general terms* to the 'resident classification system' . . .'' (emphasis added). Accordingly, we are revising these portions of the regulations text as proposed, as discussed in this final rule.

Comment: One commenter inquired about our proposed clarification in § 409.30 which, similar to the existing regulations at § 424.20(a)(1)(ii), would specify that a resident qualifies for the level of care presumption only when ''correctly'' assigned to one of the case-mix classifiers designated for this purpose. In explaining the reason for this clarification in the proposed rule (82 FR 21027), we cited a prior discussion of the presumption in the FY 2000 final rule (64 FR 41667, July 30, 1999), which had noted that ''. . . 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.'' The commenter questioned whether, in this scenario, the resident's assignment to a RUG that turns out to be incorrect would result in disqualifying the resident from SNF coverage altogether. The commenter also requested clarification in the wording of a portion of § 30.1 of the Medicare Benefit Policy Manual (MBPM), Chapter 8 that discusses how services furnished during the prior hospital stay are to be coded on the resident assessment.

Response: Regarding the scenario discussed above (in which the services that triggered a given RUG assignment on the initial assessment are found to be not reasonable and necessary), if the resident is then reassigned to a different RUG that is itself designated as meeting the level of care presumption, the resident would, in fact, still qualify for the presumption on that basis, as the end result of the reassignment would be that the resident has been ''correctly assigned'' to one of the designated RUGs on that assessment. Alternatively, if the reassignment is to one of the less intensive RUGs that is not designated as meeting the presumption, the resident would still receive an individual level of care determination using the existing administrative criteria. Finally, regarding the request to clarify the MBPM instructions on coding procedures, we believe this comment is beyond the scope of this rule. As we noted in the FY 2002 SNF PPS final rule, ''. . . specific operational instructions (such as those describing the details of particular billing procedures) are beyond the scope of the SNF PPS final rule'' (66 FR 39588, July 31, 2001). However, we will forward this comment to the appropriate component within CMS for consideration.

After consideration of the comments received, for the reasons discussed above and in the FY 2018 SNF PPS proposed rule (82 FR 21026 through 21027), we are finalizing, without modification, our proposed revisions to §§ 409.30, 413.333, 413.345, 424.20(a)(1)(ii) and (e)(2)(ii)(B)(*2*), and our revision to the title of 42 CFR part 413 as discussed in this final rule. In addition, as we proposed, we will henceforth disseminate the standard description of the administrative presumption's designated groups exclusively through the SNF PPS Web site, and will announce such designations in rulemaking only in the event that we are actually proposing to make changes in them.

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 (MAC) 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_04152015.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, the amendments enacted in section 103 of the BBRA do not 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 as is consistent with 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 2018 SNF PPS proposed rule (82 FR 21028), 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 requested 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. We note that the original BBRA amendment (as well as the implementing regulations) identified a set of excluded services by means of specifying HCPCS codes that were in effect as of a particular date (in that case, as of July 1, 1999). Identifying the excluded services in this manner made it possible for us to utilize program issuances as the vehicle for accomplishing routine updates of the excluded codes, to reflect any minor revisions that might subsequently occur in the coding system itself (for example, the assignment of a different code number to the same service). Accordingly, we stated in the proposed rule that, in the event that we identify through the current rulemaking cycle any new services that would actually represent a substantive change in the scope of the exclusions from SNF consolidated billing, we would identify these additional excluded services by means of the HCPCS codes that are in effect as of a specific date (in this case, as of October 1, 2017). By making any new exclusions in this manner, we could similarly accomplish routine future updates of these additional codes through the issuance of program instructions.

In the proposed rule, we noted that one category of services which consolidated billing excludes under § 411.15(p)(3) consists of certain exceptionally intensive types of outpatient hospital services. As we explained in the FY 2000 SNF PPS final rule, this exclusion applies to ''. . . those types of outpatient hospital services that *we specifically identify* as being beyond the scope of SNF care plans generally'' (64 FR 41676, July 30, 1999, emphasis added). As discussed in the FY 2018 SNF PPS proposed rule (82 FR 21028), to further clarify this longstanding policy noted above that the outpatient hospital exclusion applies solely to those services that we specifically designate for this purpose, we proposed to revise § 411.15(p)(3)(iii) to state this more explicitly. In addition, we note that recent revisions in the long-term care facility requirements for participation (81 FR 68858, October 4, 2016) have moved the comprehensive care plan regulations from their previous location at § 483.20(k) to a new, redesignated § 483.21(b); accordingly, we proposed to make a conforming revision in the existing cross-reference to that provision that appears in § 411.15(p)(3)(iii).

We did not receive any public comments on our proposed revisions to § 411.15(p)(3)(iii). Therefore, for the reasons discussed in this final rule and in the FY 2018 SNF PPS proposed rule, we are finalizing our revisions to § 411.15(p)(3)(iii) as proposed, without modification.

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 that, rather than specifying those particular items and services that are excluded from SNF consolidated billing, CMS should comprehensively identify the full range of items and services that are subject to this provision.

Response: We note that the online listing by HCPCS code of those services that are excluded from consolidated billing (in the annual updates that are posted at *https://www.cms.gov/Medicare/Billing/SNFConsolidatedBilling/index.html*) follows the overall structure of the statutory provision itself. This statutory provision, in turn, specifies in section 1888(e)(2)(A)(ii) through (iv) of the Act those particular services that are *excluded* from it, so that any services not so specified would remain subject to the provision (this follows the similar structure that was originally established in the hospital bundling provision at section 1862(a)(14) of the Act, which served as the model for SNF consolidated billing). As discussed in the General Explanation of the Major Categories (available online at *https://www.cms.gov/Medicare/Billing/SNFConsolidatedBilling/Downloads/2017-General-Explanation.pdf*), one exception to this overall pattern involves the administrative carve-out from SNF consolidated billing under 42 CFR 411.15(p)(3)(iii) for ambulatory surgical services performed in the outpatient hospital setting (Major Category I.F):

> Inclusions, rather than exclusions, are given in this one case, because of the great number of surgery procedures that are excluded and can only be safely performed in a hospital operating room setting. It is easier to automate edits around the much shorter list of inclusions under this category, representing *minor procedures that can be performed in the SNF itself* (emphasis in the original).

Comment: We received a number of comments regarding the statutory exclusion from consolidated billing for certain high-intensity chemotherapy drugs and the administrative exclusion for certain high-intensity outpatient hospital services. One commenter in particular expressed continuing dissatisfaction with what it characterized as CMS's ''inadequate regulatory action'' in modifying the consolidated billing requirement to

reflect the introduction of expensive new drugs, and the expanded provision of outpatient services in nonhospital settings. The commenter cited as examples some previous comments that it had submitted during the FY 2004 rulemaking cycle, in which it had recommended the exclusion of certain additional chemotherapy drugs, and the expansion of the existing administrative exclusion for certain high-intensity outpatient hospital services to encompass freestanding (nonhospital) settings as well. Regarding the latter recommendation, the commenter indicated that to date, CMS has not revisited this ''site of service'' rule.

Response: Regarding the commenter's previous recommendation during the FY 2004 rulemaking cycle for additional chemotherapy exclusions, our response in the FY 2004 final rule (68 FR 46060, August 4, 2003) explained that ''. . . most of the chemotherapy drugs . . . mentioned by commenters were considered for exclusion under the BBRA, but were not adopted by the Congress in the BBRA list of excluded items and services.'' As further explained in several subsequent rulemaking cycles (most recently, in the FY 2016 final rule (80 FR 46407, August 4, 2015)),

> . . . our position has always been that the BBRA's discretionary authority to exclude codes within certain designated service categories applies solely to codes that were created subsequent to the BBRA's enactment, and not to those codes that were already in existence as of July 1, 1999 (the date that the legislation itself uses as the reference point for identifying the codes that it designates for exclusion). As we explained in the FY 2010 final rule (74 FR 40354), this position reflects the assumption that if a particular code was already in existence as of that date but not designated for exclusion, this meant that it was intended to remain within the SNF PPS bundle, subject to the BBRA Conference Report's provision for a GAO review of the code set that was conducted the following year (H.R. Rep. 106–479 at 854 (1999) (Conf. Rep.)).

Further, we note that we have indeed continued to solicit recommendations periodically for additional exclusions within those specified service categories (such as chemotherapy services) for which the law authorizes us to do so, and we have, in fact, adopted those recommendations to the extent that the recommended services meet the applicable criteria for exclusion.

With regard to the administrative exclusion for high-intensity outpatient hospital services, we note that we not only addressed this issue in the FY 2004 final rule itself (68 FR 46061, August 4, 2003) but, as discussed below, we have revisited it repeatedly in subsequent rulemaking in response to the recurring public comments that we have received on the issue since that time. For example, the FY 2014 final rule (78 FR 47957 through 47958, August 6, 2013) cited the explanation in numerous previous rules (along with Medicare Learning Network (MLN) Matters article SE0432, available online at *https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/SE0432.pdf*) that ''. . . the rationale for establishing this exclusion was to address those types of services that are so far beyond the normal scope of SNF care that they *require the intensity of the hospital setting* in order to be furnished safely and effectively'' (emphasis in the original), and also noted that when the Congress enacted the consolidated billing exclusion for certain RHC and FQHC services in section 410 of the MMA, the accompanying legislative history's description of present law directly acknowledged the hospital-specific nature of this exclusion. In addition, the FY 2012 final rule (76 FR 48532, August 8, 2011) indicated that ever since its inception, this exclusion was intended to be hospital-specific: It cited the applicable discussion in the May 12, 1998 interim final rule (63 FR 26298), which explained that this exclusion was created within the context of the concurrent development of a new PPS specifically for outpatient hospital services, reflecting the need ''. . . to delineate the respective areas of responsibility for the SNF under the Consolidated Billing provision, and for the hospital under the outpatient bundling provision, with regard to these services.'' This point was further reinforced in the subsequent final rule for FY 2000 (64 FR 41676, July 30, 1999), which noted that

> . . . a key concern underlying the development of the consolidated billing exclusion of certain outpatient hospital services specifically involves the need to distinguish those services that comprise the SNF bundle from those that will become part of the outpatient hospital bundle that is currently being developed in connection with the outpatient hospital PPS. Accordingly, we are not extending the outpatient hospital exclusion from consolidated billing to encompass any other, freestanding settings.

Finally, the FY 2010 final rule (74 FR 40355, August 11, 2009), while acknowledging that advances in medical technology over time may make it feasible to perform such high-intensity outpatient services more widely in nonhospital settings, then went on to cite the FY 2006 final rule in noting that such a development ''. . . would not argue in favor of excluding the nonhospital performance of the service from consolidated billing, . . . but rather, would call into question whether the service should continue to be excluded from consolidated billing at all, even when performed in the hospital setting'' (70 FR 45049, August 4, 2005).

Comment: One commenter reiterated a recommendation made in previous rulemaking cycles to exclude the oral chemotherapy drug Revlimid® (lenalidomide).

Response: We note that a discussion of our decision not to adopt the exclusion recommendations regarding this drug appears in the final rule for FY 2015 (79 FR 45641 through 45642, August 5, 2014), which was also referenced in the FY 2017 final rule (81 FR 51985, August 5, 2016) as well.

Comment: Several commenters reiterated the same set of comments that they had submitted previously during last year's rulemaking cycle, which had noted the importance of continuing to exclude certain customized prosthetic devices from consolidated billing, and urged expanding that exclusion to encompass orthotics as well. These commenters had also recommended the following four HCPCS codes for exclusion: 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. One of the commenters now noted in addition that although our previous response in the FY 2017 final rule (81 FR 51986, August 5, 2016) had indicated 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,'' the commenter has been unable to locate this code on the list of exclusions in the 2017 Annual Part B MAC Update.

Response: We refer to the previous discussion in the FY 2017 final rule (81 FR 51986, August 5, 2016) regarding our decision not to adopt the recommendations for excluding orthotics and HCPCS codes L5010, L5020, and L5987. In addition, while that final rule was correct in noting that ever since its initial assignment, code L5969 has appeared as an exclusion under Major Category III.D. (''Customized Prosthetic Devices'') in the Annual Part A MAC Update, this

particular code was inadvertently omitted from the corresponding exclusion list in File 1 of the Annual Part B MAC Update. We appreciate being apprised of the omission, and will take the necessary steps to rectify this oversight.

Comment: One commenter made reference to high-cost medications that are currently not excluded from consolidated billing, and requested guidance in this context regarding the applicable policy on residents being requested to supply their own medications to minimize the cost to the nursing home.

Response: In terms of Medicare payment, with limited exceptions (such as certain specified, high-intensity chemotherapy drugs), medications that are required during the course of a Medicare-covered SNF stay are included within the SNF's bundled per diem payment for the covered stay itself, which the SNF is required under the terms of its provider agreement to accept as payment in full (see section 1866(a)(1)(A)(i) of the Act and the implementing regulations at § 489.21(a)). Further, § 489.20(s) requires the SNF to furnish these bundled services either directly with its own resources, or under an ''arrangement'' in which the SNF itself accepts the professional and financial responsibility for the arranged-for services (see the discussion of arrangements that appears in § 409.3 and in § 10.3 of the Medicare General Information, Eligibility, and Entitlement Manual, Chapter 5). Section 489.21(h) further indicates that even if an SNF fails to furnish directly or make arrangements for such a service, the beneficiary is not to bear the financial liability for the service.

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, SNF-level 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 final 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.* We received no comments on this aspect of the proposed rule.

D. Other Issues

1. Revising and Rebasing the SNF Market Basket Index

Section 1888(e)(5)(A) of the Act requires the Secretary to establish a market basket index that reflects the 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 in section III.B. of this rule, to update the SNF PPS per diem rates and to determine the labor-related share on an annual basis.

The SNF market basket is a fixed-weight, Laspeyres-type price index. A Laspeyres price index measures the change in price, over time, of the same mix of goods and services purchased in the base period. Any changes in the quantity or mix of goods and services (that is, intensity) purchased over time relative to a base period are not measured.

The index itself is constructed in three steps. First, a base period is selected (in the FY 2018 SNF PPS proposed rule (82 FR 21029), the proposed base period was 2014) and total base period expenditures are estimated for a set of mutually exclusive and exhaustive spending categories with the proportion of total costs that each category represents being calculated. These proportions are called cost or expenditure weights. Second, each expenditure category is matched to an appropriate price or wage variable, referred to as a price proxy. In nearly every instance, these price proxies are derived from publicly available statistical series that are published on a consistent schedule (preferably at least on a quarterly basis). Finally, the expenditure weight for each cost category is multiplied by the level of its respective price proxy. The sum of these products (that is, the expenditure weights multiplied by their price levels) for all cost categories yields the composite index level of the market basket in a given period. Repeating this step for other periods produces a series of market basket levels over time. Dividing an index level for a given period by an index level for an earlier period produces a rate of growth in the input price index over that timeframe.

Effective for cost reporting periods beginning on or after July 1, 1998, we revised and rebased our 1977 routine costs input price index and adopted a total expenses SNF input price index using FY 1992 as the base year. In the FY 2002 SNF PPS final rule (66 FR 39582), we rebased and revised the market basket to a base year of FY 1997. In the FY 2008 SNF PPS final rule (72 FR 43425), we rebased and revised the market basket to a base year of FY 2004. In the FY 2014 SNF PPS final rule (78 FR 47939), we last revised and rebased the SNF market basket, which included updating the base year from FY 2004 to FY 2010. For FY 2018, we proposed (82 FR 21029) to rebase the market basket to reflect 2014 Medicare-allowable total cost data (routine, ancillary, and capital-related) from freestanding SNFs and to revise applicable cost categories and price proxies used to determine the market basket. We proposed to maintain our policy of using data from freestanding SNFs, which represent 93 percent of the total SNFs shown in Table 26. We believe using freestanding MCR data, as opposed to the hospital-based SNF MCR data, for the proposed cost weight calculation is most appropriate because of the complexity of hospital-based data and the representativeness of the freestanding data. Hospital-based SNF expenses, are embedded in the hospital cost report. Any attempt to incorporate data from hospital-based facilities requires more complex calculations and assumptions regarding the ancillary costs related to the hospital-based SNF unit. We believe the use of freestanding SNF cost report

data is technically appropriate for reflecting the cost structures of SNFs serving Medicare beneficiaries.

We proposed to use 2014 as the base year as we believe that the 2014 Medicare cost reports represented the most recent, complete set of Medicare cost report (MCR) data available to develop cost weights for SNFs at the time of rulemaking. The 2014 Medicare cost reports are for cost reporting periods beginning on and after October 1, 2013 and before October 1, 2014. While these dates appear to reflect fiscal year data, we note that a Medicare cost report that begins in this timeframe is generally classified as a ''2014 cost report.'' For example, we found that of the available 2014 Medicare cost reports for SNFs, approximately 7 percent had an October 1, 2013 begin date, approximately 70 percent of the reports had a January 1, 2014 begin date, and approximately 12 percent had a July 1, 2014 begin date. For this reason, and for the reasons explained below, we proposed to define the base year of the market basket as ''2014-based'' instead of ''FY 2014-based''.

Specifically, we proposed to develop cost category weights for the 2014-based SNF market basket in two stages. First, we proposed to derive eight major expenditures or cost weights from the 2014 MCR data (CMS Form 2540–10) for freestanding SNFs: Wages and Salaries; Employee Benefits; Contract Labor; Pharmaceuticals; Professional Liability Insurance; Home Office Contract Labor; Capital-related; and a residual ''All Other''. With the exception of the Home Office Contract Labor cost weight, these are the same cost categories calculated using the 2010 MCR data for the FY 2010-based SNF market basket. We provided a detailed discussion of our proposal to use the 2014 MCR data to determine the Home Office Contract Labor cost weight in section IV.A.1.a of the proposed rule and in section III.D.1.a of this final rule. The residual ''All Other'' category would reflect all remaining costs that are not captured in the other seven cost categories. Second, we proposed to divide the residual ''All Other'' cost category into subcategories using U.S. Department of Commerce Bureau of Economic Analysis' (BEA) 2007 Benchmark Input-Output (I–O) ''use table before redefinitions, purchaser's value'' for the Nursing and Community Care Facilities industry (NAICS 623A00) aged forward to 2014 using price changes. Furthermore, we proposed to continue to use the same overall methodology as was used for the FY 2010-based SNF market basket to develop the capital related cost weights of the 2014-based SNF market basket. We note that we are no longer referring to the market basket as a ''FY 2014-based'' market basket and instead refer to the market basket as simply ''2014-based.'' We proposed this change in naming convention for the market basket because the base year cost weight data for the proposed market basket do not reflect strictly fiscal year data. For example, the 2014-based SNF market basket uses Medicare cost report data and other government data that reflects fiscal year 2014, calendar year 2014, and state fiscal year 2014 expenses to determine the base year cost weights. Given that it is based on a mix of classifications of 2014 data, we proposed to refer to the market basket simply as ''2014-based'' as opposed to a ''FY 2014-based'' or ''CY 2014-based''.

We refer readers to the FY 2018 SNF PPS proposed rule (82 FR 21029 through 21041) for a complete discussion of our proposals and associated rationale related to revising and rebasing the SNF market basket. We received a number of comments on the proposed revising and rebasing of the SNF market basket. A discussion of these comments, with our responses, appears throughout this section.

Comment: Several commenters supported the rebasing and revising of the SNF market basket from base year 2010 to base year 2014, stating that the weights for calculating the market basket update should reflect the most up-to-date cost data available. Other commenters requested that we meet with certain health care association representatives before we move forward with the proposed rebasing of the SNF market basket for FY 2018.

Response: We appreciate the commenters' support to rebase the market basket to 2014. We believe that it is reasonable and appropriate to rebase the market basket to 2014 as we believe this reflects the most complete and up-to-date cost data available. We note that we are available to meet with interested parties upon request to discuss their research and ideas for future rebasings.

Comment: Several commenters requested that we align the rebasing schedule of the SNF market basket with the acute inpatient hospital market basket rebasing schedule. They claimed that updating the SNF market basket schedule will improve the accuracy of the SNF market basket updates, particularly since the SNF wage index is directly linked to the hospital wage index. One commenter requested we provide information on ways to work collaboratively with the industry to develop an alternative approach to the SNF market basket methodology and to more appropriately update weights using more current data on a rolling basis. The commenter requested an explanation of why a chained index, which updates cost weights on a continual basis is not employed instead of a fixed-weight index approach.

Response: We appreciate the commenters' suggestion to align the rebasing schedule of the SNF market basket with the acute inpatient hospital market basket rebasing schedule. As discussed in the FY 2006 IPPS final rule (70 FR 47407), in accordance with section 404 of Public Law 108–173, we established a rebasing frequency of every four years for the IPPS hospital market basket. We last rebased the SNF market basket four years ago, reflecting a FY 2010 base year, in the FY 2014 SNF PPS final rule (78 FR 47939). We will continue to monitor the major cost share weights derived from the Medicare cost reports to evaluate whether a rebasing of the SNF market basket is necessary and may consider rebasing the SNF market basket consistent with the IPPS rebasing schedule.

In regards to the use of a fixed-weight index approach, we have found that healthcare provider cost share weights do not change substantially on an annual basis and, therefore, the use of a Laspeyres index formula, with base year weights updated on a regular basis (such as every few years), is technically appropriate for the CMS market baskets. In a 2008 paper,[1] the CMS Office of the Actuary (OACT) investigated the impact of using an alternative price index formula on the inpatient hospital market basket and concluded that market basket rebasings more frequent than every 5 years would not result in any significant changes in update factors. This study also found that the use of an alternative index formula, such as a Paasche, Fisher, or Tornqvist, would not lead to an appreciable change to the results.

a. Development of Cost Categories and Weights

i. Use of Medicare Cost Report Data To Develop Major Cost Weights

To create a market basket that is representative of freestanding SNF providers serving Medicare patients and to help ensure accurate major cost weights (which is the percent of total Medicare allowable costs, as defined below), we proposed to apply edits to remove reporting errors and outliers. Specifically, the SNF Medicare cost

[1] *https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/MedicareProgramRatesStats/Downloads/alternativeindexweights.pdf.*

reports used to calculate the market basket cost weights excluded any providers that reported costs less than or equal to zero for the following categories: Total facility costs; total operating costs; Medicare general inpatient routine service costs; and Medicare PPS payments. The final sample used included roughly 96 percent of those providers who submitted a Medicare cost report for 2014.

Additionally, for each of the major cost weights, except the Home Office Contract Labor cost weight (Wages and Salaries, Employee Benefits, Contract Labor, Pharmaceuticals, Professional Liability Insurance, and Capital-related Expenses) the data were trimmed to remove outliers (a standard statistical process) by: (1) Requiring that major expenses (such as Wages and Salaries costs) and total Medicare-allowable costs are greater than zero; and (2) excluding the top and bottom five percent of the major cost weight (for example, Wages and Salaries costs as a percent of total Medicare-allowable costs).

We note that in the FY 2018 SNF PPS proposed rule, we mistakenly referenced that we used the same trimming methodology for the Home Office Contract Labor cost weight that we used for the other major cost weights (a top and bottom five percent trimming methodology).

For the Home Office Contract Labor cost weight, we applied a one percent top-only trimming methodology. This allowed all providers' Medicare-allowable costs to be included, even if their home office contract labor costs were zero. We believe, as the Medicare cost report data (Worksheet S2 line 45) indicate, that not all SNF providers have a Home Office. Providers without a Home Office can incur these expenses directly by having their own staff, for which the costs would be included in the Wages and Salaries and Benefits cost weights. Alternatively, providers without a Home Office could also purchase related services from external contractors for which these expenses would be captured in the residual ''All-Other'' cost weight. We believe this one percent top-only trimming methodology is appropriate as it addresses outliers while allowing providers with zero Home Office Contract Labor costs to be included in the Home Office Contract Labor cost weight calculation. If we applied both top and bottom five percent trimming methodology we would exclude providers who have zero Home Office Contract Labor costs.

The major cost weight trimming process is done for each cost weight individually and, therefore, providers excluded from one cost weight calculation are not automatically excluded from other cost weight calculations. These were the same types of edits utilized for the FY 2010-based SNF market basket (with the exception of the Home Office Contract Labor cost weight which was not broken out using Medicare Cost Reports for the FY 2010 based SNF market basket), as well as other PPS market baskets (including but not limited to IPPS market basket and HHA market basket). We believe this trimming process improves the accuracy of the data used to compute the major cost weights by removing possible data misreporting.

Finally, the final weights of the proposed 2014-based SNF market basket were based on weighted means. For example, the final Wages and Salaries cost weight after trimming is equal to the sum of total Medicare-allowable wages and salaries divided by the sum of total Medicare-allowable costs. This methodology is consistent with the methodology used to calculate the FY 2010-based SNF market basket cost weights and other PPS market basket cost weights.

As stated above, the major cost weights of the 2014-based SNF market basket were derived from 2014 MCR data that is reported on CMS Form 2540–10, effective for freestanding SNFs with a cost reporting period beginning on or after December 1, 2010. The major cost weights for the FY 2010-based SNF market basket were derived from the 2010 MCR data that is reported on CMS Form 2540–96. CMS Form 2540–96 was effective for freestanding SNFs with cost reporting periods beginning on and after October 1, 1997. The OMB control number for both Form 2549–10 and Form 2540–96 is 0938–0463.

For all of the cost weights, we proposed to use Medicare allowable-total costs as the denominator (that is, Wages and Salaries cost weight = Wages and Salaries costs divided by Medicare-allowable total costs). Medicare-allowable total costs were proposed to be equal to total costs (after overhead allocation) from Worksheet B part 1, column 18, for lines 30, 40 through 49, 51, 52, and 71 plus Medicaid drug costs as defined below. We also proposed to include estimated Medicaid drug costs in the pharmacy cost weight, as well as the denominator for total Medicare-allowable costs. This is the same methodology used for the FY 2010-based SNF market basket and the FY 2004-based SNF market basket. The inclusion of Medicaid drug costs was finalized in the FY 2008 SNF PPS final rule (72 FR 43425 through 43430), and for the same reasons set forth in that final rule, we proposed to continue to use this methodology in the 2014-based SNF market basket.

We proposed that for the 2014-based SNF market basket we obtain costs for one new major cost category from the Medicare cost reports that was not used in the FY 2010-based SNF market basket—Home Office Contract Labor Costs.

We described the detailed methodology for obtaining costs for each of the eight major cost categories in section V.A.1.a. of the FY 2018 SNF PPS proposed rule (82 FR 21030) and below in section III.D.1.a. of this rule. The methodology used is similar to the methodology used in the FY 2010-based SNF market basket, as described in the FY 2014 SNF PPS final rule (78 FR 47940 through 47942).

(1) *Wages and Salaries:* To derive Wages and Salaries costs for the Medicare-allowable cost centers, we proposed first to calculate total unadjusted wages and salaries costs as reported on Worksheet S–3, part II, column 3, line 1. We then proposed to remove the wages and salaries attributable to non-Medicare-allowable cost centers (that is, excluded areas), as well as a portion of overhead wages and salaries attributable to these excluded areas. Excluded area wages and salaries were equal to wages and salaries as reported on Worksheet S–3, part II, column 3, lines 3, 4, and 7 through 11 plus nursing facility and non-reimbursable salaries from Worksheet A, column 1, lines 31, 32, 50, and 60 through 63.

Overhead wages and salaries are attributable to the entire SNF facility; therefore, we proposed to include only the proportion attributable to the Medicare-allowable cost centers. We proposed to estimate the proportion of overhead wages and salaries that is attributable to the non-Medicare-allowable costs centers (that is, excluded areas) by multiplying the ratio of excluded area wages and salaries (as defined above) to total wages and salaries as reported on Worksheet S–3, part II, column 3, line 1 by total overhead wages and salaries as reported on Worksheet S3, Part III, column 3, line 14. We used a similar methodology to derive wages and salaries costs in the FY 2010-based SNF market basket.

(2) *Employee Benefits:* We proposed Medicare-allowable employee benefits to be equal to total benefits as reported on Worksheet S–3, part II, column 3, lines 17 through 19 minus non-Medicare-allowable (that is, excluded area) employee benefits and minus a portion of overhead benefits attributable

to these excluded areas. Non-Medicare-allowable employee benefits were derived by multiplying total excluded wages and salaries (as defined above in the 'Wages and Salaries' section) times the ratio of total benefit costs as reported on Worksheet S–3, part II, column 3, lines 17 through 19 to total wages and salary costs as reported on Worksheet S3, part II, column 3, line 1. Likewise, the portion of overhead benefits attributable to the excluded areas was derived by multiplying overhead wages and salaries attributable to the excluded areas (as defined in the 'Wages and Salaries' section) times the ratio of total benefit costs to total wages and salary costs (as defined above). We used a similar methodology in the FY 2010-based SNF market basket.

(3) *Contract Labor:* We proposed to derive Medicare-allowable contract labor costs from Worksheet S–3, part II, column 3, line 17. We note that in the FY 2018 SNF PPS proposed rule (82 FR 21030), we mistakenly referenced line 17. These costs are actually reported in Worksheet S–3, part II, column 3, line 14 as per the CMS Form 2540–10 instructions (which reflects costs for contracted direct patient care services, that is, nursing, therapeutic, rehabilitative, or diagnostic services furnished under contract rather than by employees and management contract services). We note that the processing of the data was correct. We used Worksheet S–3, part II, column 3, line 14 in our analysis. Our written description in the proposed rule of the line we used was, however, incorrect.

(4) *Pharmaceuticals:* We proposed to calculate pharmaceuticals costs using the non-salary costs from the Pharmacy cost center (Worksheet B, part I, column 0, line 11 less Worksheet A, column 1, line 11) and the Drugs Charged to Patients' cost center (Worksheet B, part I, column 0, line 49 less Worksheet A, column 1, line 49). Since these drug costs were attributable to the entire SNF and not limited to Medicare-allowable services, we proposed to adjust the drug costs by the ratio of Medicare-allowable pharmacy total costs (Worksheet B, part I, column 11, for lines 30, 40 through 49, 51, 52, and 71) to total pharmacy costs from Worksheet B, part I, column 11, line 11. Worksheet B, part I allocates the general service cost centers, which are often referred to as ''overhead costs'' (in which pharmacy costs are included) to the Medicare-allowable and non-Medicare-allowable cost centers. This adjustment was made for those providers who reported Pharmacy cost center expenses. Otherwise, we assumed the non-salary Drugs Charged to Patients costs were Medicare-allowable.

Second, similar to the FY 2010-based SNF market basket, we proposed to continue to adjust the drug expenses reported on the MCR to include an estimate of total Medicaid drug costs, which are not represented in the Medicare-allowable drug cost weight. Similar to the FY 2010-based SNF market basket, we estimated Medicaid drug costs based on data representing dual-eligible Medicaid beneficiaries. Medicaid drug costs were estimated by multiplying Medicaid dual-eligible drug costs per day times the number of Medicaid days as reported in the Medicare-allowable skilled nursing cost center (Worksheet S3, part I, column 5, line 1) in the SNF MCR. Medicaid dual-eligible drug costs per day (where the day represents an unduplicated drug supply day) were estimated using a sample of 2014 Part D claims for those dual-eligible beneficiaries who had a Medicare SNF stay during the year. Medicaid dual-eligible beneficiaries would receive their drugs through the Medicare Part D benefit, which would work directly with the pharmacy and, therefore, these costs would not be represented in the Medicare SNF MCRs. A random twenty percent sample of Medicare Part D claims data yielded a Medicaid drug cost per day of $19.62. We note that the FY 2010-based SNF market basket also relied on data from the Part D claims, which yielded a dual-eligible Medicaid drug cost per day of $17.39 for 2010.

Provided below are summaries of the comments we received related to the Pharmaceuticals cost category, as well as our responses.

Comment: One commenter was concerned with the lower Pharmaceuticals cost weight in the 2014-based SNF market basket compared to the 2010-based SNF market basket. They were unable to explain the decrease given their experience with annual pharmaceutical price increases and the introduction of new pharmaceuticals.

Several commenters also had specific concerns regarding the methodology utilized to determine the Pharmaceuticals cost weight. The commenters stated that the vast majority of SNFs did not report costs on the cost report line for the ''Pharmacy'' department. They stated that only a small number of SNFs have in-house Pharmacies and that those SNFs were used as a proxy for the pharmaceutical costs for all SNFs; one commenter requested an alternative method.

Several commenters were also concerned by the addition of estimated Part D medication costs to the ''Drugs Charged to Patients'' data reported on Row 49 of the cost report. The commenter questioned why this type of ''gross up'' was not, as far as they could tell, applied to any of the other ancillary cost centers.

Response: The methodology used to determine the cost weights in the 2014-based SNF market basket and 2010-based SNF market basket is the same. The change in the Pharmaceuticals cost weight in the 2014-based SNF market basket (7.3 percent) from the FY 2010-based SNF market basket (7.9 percent) is a function of the growth rate of pharmaceutical expenses relative to other components of the market basket over this time period. Our own internal analysis shows increasing drug costs from FY 2010 to FY 2014; however, during this time period, pharmaceutical costs increased at a slower rate than other components of the market basket—such as capital and contract labor expenses. This relative comparison resulted in a decrease in the Pharmaceuticals cost weight of 0.6 percentage point between the FY 2010-based SNF market basket and 2014-based SNF market basket (7.9 percent to 7.3 percent) while the capital cost weight increased 0.5 percentage point (7.4 percent to 7.9 percent) and contract labor grew 1.3 percentage points (5.5 percent to 6.8 percent). It is also important to consider that the increase in pharmaceutical costs over this period reflects changes in both the price of prescription drugs, proxied by the Producer Price Index for Prescription Drugs, as well the quantity and intensity of prescriptions. Our analysis of the data shows that the decrease in the Pharmaceuticals cost weight was consistent, in aggregate, across urban and rural status SNFs as well as across for-profit, government, and nonprofit ownership type SNFs.

As stated above and in the FY 2018 SNF PPS proposed rule (82 FR 21030 through 21031), we proposed to calculate pharmaceutical costs using the non-salary costs reported in the Pharmacy cost center (Worksheet B, part I, column 0, line 11 less Worksheet A, column 1, line 11) and the Drugs Charged to Patients' cost center (Worksheet B, part I, column 0, line 49 less Worksheet A, column 1, line 49), hereafter referred to as total MCR drug costs. Since these drug costs were attributable to the entire SNF and not limited to Medicare-allowable services, we proposed to adjust the drug costs by the ratio of Medicare-allowable pharmacy total costs (Worksheet B, part I, column 11, for lines 30, 40 through 49, 51, 52, and 71) to total pharmacy

costs (Worksheet B, part I, column 11, line 11).

We understand the commenter's concern regarding the adjustment to the total MCR drug costs using the Pharmacy cost center as only 20 percent of providers reported Pharmacy cost center expenses. We are clarifying that the adjustment was only applied to those 20 percent of providers who reported Pharmacy costs. We assumed that all of the drug costs were Medicare-allowable for the remaining 80 percent of providers. We added a clarifying sentence in the Pharmacy cost weight calculation of this final rule. Applying this adjustment had only a marginal impact on the drug cost weight (lowering it by only 0.1 percentage point). As a sensitivity, we also derived an alternative by using the ratio of Skilled Nursing Facility days (as reported on Worksheet S3, part 1, column 7 line 1) to Total Facility days. This would result in a Pharmaceuticals cost weight of 7.1 percent compared to the 2014-based cost weight of 7.3 percent.

As stated in the proposed rule (82 FR 21031), the 2014-based SNF market basket included an adjustment to the drug expenses reported on the MCR to include an estimate of total Medicaid drug costs, which are not represented in the Medicare-allowable drug cost weight. As stated above, the 2014-based SNF market basket reflects total Medicare allowable costs (that is, total costs for all payers for those services reimbursable under the SNF PPS). For the FY 2006-based SNF market basket (72 FR 43426), commenters noted that the total pharmaceutical costs reported on the MCR did not include pharmaceutical costs for dual-eligible Medicaid patients as these were directly reimbursed by Medicaid. Since all of the other cost category weights reflect Medicaid patients (including the compensation costs for dispersing these drugs), we made an adjustment to include these drug expenses. The pharmaceutical cost weight using only 2014 MCR data without any adjustments is 3.0 percent, compared to the proposed Pharmaceuticals cost weight (including the adjustment for Medicaid dual-eligible drug costs) of 7.3 percent.

Comment: One commenter requested further explanation on how Part D drug costs were incorporated into the Pharmaceuticals cost weight. They questioned how the 20 percent sample was selected and the rationale for selecting this population to estimate non-SNF Medicaid drug costs. They questioned if there were analytics to support these decisions and also requested clarification for why the drug costs for patients with a SNF stay would be comparable to patients in a nursing facility that had not had a hospitalization during the year. They also questioned whether the Part D claims were matched to the SNF stay and if Part D claims for the SNF stay were excluded. They further questioned which cost variables in Part D claims were used, how the costs per day were calculated and the rationale for producing this estimate.

Response: As stated previously in this section, the 2014-based SNF market basket reflects total Medicare allowable costs (that is, total costs for all payers for those services reimbursable under the SNF PPS). For the FY 2006-based SNF market basket (72 FR 43426), commenters noted that the total pharmaceutical costs reported on the MCR did not include pharmaceutical costs for dual-eligible Medicaid patients as these were directly reimbursed by Medicaid. Since all of the other cost category weights reflect Medicaid patients (including the compensation costs for dispensing these drugs), we made an adjustment to include these Medicaid drug expenses so the market basket cost weights would be calculated consistently.

For the 2014-based SNF market basket, as stated in the FY 2018 SNF PPS proposed rule (82 FR 21031), we estimated Medicaid drug costs by multiplying Medicaid dual-eligible drug costs per day times the number of Medicaid days as reported in the Medicare-allowable skilled nursing facility cost center (Worksheet S3, part I, column 5, line 1) on the SNF MCR. The Medicaid dual-eligible drug costs per day (where the day represents an unduplicated drug supply day) were estimated using a random 20 percent sample of 2014 Part D claims for those dual-eligible beneficiaries who had a Medicare SNF stay during the year. We believe this sample is a reasonable proxy for total drug costs per day for Medicaid patients residing in a skilled nursing unit under a Medicaid stay. Our analysis of the Part D claims data shows that dual-eligible beneficiaries have higher drug costs per day than ''non-duals'' and that dual-eligible beneficiaries who have had a SNF Part A stay during the year have higher drug costs per day ($19.62) compared to those dual-eligible beneficiaries with no SNF Part A stay during the year ($14.82).

The total drug costs per unduplicated day represented all drug costs incurred during the 2014 calendar year for those dual-eligible beneficiaries with a SNF Medicare stay during that 2014 calendar year. Therefore, they include drug costs incurred during the Medicaid SNF stay occurring in the 2014 calendar year. The total drug costs from the Part D claims includes the drug ingredient cost, the dispensing fee, vaccine administration fee and sales tax. We used a 20 percent sample of Part D claims (approximately 287 million claims) where claims were randomly selected based on the beneficiary ID number.

Comment: One commenter stated that they see an increase in the number of Veterans being served by SNFs. They further stated that Medicare patients, if they were admitted to a non-VA nursing home, would use their Medicare benefit. However, in a VA home, the commenter claimed that the patient would use their VA benefit which covers the drug costs—and not the nursing home. The commenter concluded that there would be many drug costs that are not represented on the cost report that traditionally would have been. The commenter requested clarification on how we will address this challenge.

Response: We appreciate the commenter raising this concern. We believe the current methodology and resulting Pharmaceutical cost weight is reasonable, in part because VA costs would not have a significant impact on the market basket cost weights (according to the CMS National Health Expenditure Accounts, VA spending accounted for roughly 3 percent of total Nursing Care Facilities and Continuing Care Retirement Communities expenditures in 2014). However, in the future we plan to monitor this issue in more depth to ensure the market basket is adequately capturing the appropriate costs.

(5) *Professional Liability Insurance:* We proposed to calculate the professional liability insurance costs from Worksheet S–2 of the MCRs as the sum of premiums; paid losses; and self-insurance (Worksheet S–2, column 1 through 3, line 41).

Provided below are summaries of the comments we received related to the Professional Liability Insurance cost category, as well as our responses.

Comment: One commenter stated that we should calculate a weight for professional liability insurance considering other data sources. As an example, the commenter provided a link to AHCA's Aon Professional Liability Study stating that the 2016 report documents a significant and continual increase in professional liability costs.

Response: We thank the commenter for providing the link to this study. As stated in the FY 2018 SNF proposed rule (82 FR 21031), the professional liability insurance cost weight is derived using data from Worksheet S–2

of the Medicare Cost Reports. These data represent the sum of premiums, paid losses, and self-insurance (Worksheet S–2, column 1 through 3, line 41). We continue to believe that using these data submitted by SNFs on the Medicare cost report represent the best data source to derive the professional liability insurance cost weight. We will continue to evaluate other data sources, including the study provided by the commenter, to obtain additional information regarding professional liability insurance costs for SNFs.

(6) *Capital-Related:* We proposed to derive the Medicare-allowable capital-related costs from Worksheet B, part II, column 18 for lines 30, 40 through 49, 51, 52, and 71.

(7) *Home Office Contract Labor Costs:* We proposed to calculate Medicare-allowable home office contract labor costs by multiplying total home office contract labor costs (as reported on Worksheet S3, part 2, column 3, line 16) times the ratio of Medicare-allowable operating costs (Medicare-allowable total costs less Medicare-allowable capital costs) to total operating costs (equal to Worksheet B, part I, column 18, line 100 less Worksheet B, part I, column 0, line 1 and 2).

(8) *All Other (residual):* We proposed to calculate the ''All Other'' cost weight as a residual, calculated by subtracting the major cost weights (Wages and Salaries, Employee Benefits, Contract Labor, Pharmaceuticals, Professional Liability Insurance, Home Office Contract Labor, and Capital-Related) from 100.

Provided below are summaries of the general comments we received related to the major cost category weights, as well as our responses.

Comment: One commenter noted that the decrease in cost weights related to wages, benefits, contract labor, and pharmaceuticals from FY 2010 to the proposed base year of 2014 did not reflect, in any way, their experience. For geographic locations that have a large proportion of staff whose wages and benefits are driven by collective bargaining agreements, such as the NY metropolitan area where providers have seen regular cost increases over the 4 years, the commenter claimed that the decrease in cost weight does not make sense.

Response: The purpose of the SNF market basket is to measure the price inflation facing average SNFs serving Medicare beneficiaries at the national level. A change in the Wages and Salaries cost weight is a function of the growth rate of Wages and Salaries expenses relative to other components of the market basket, based on data directly supplied to CMS by SNFs. We would further note that differences in wage and wage-related costs among geographic regions are accounted for by the application of the wage index.

Comment: One commenter requested we show the numerators and denominators for the calculation of each weight so that it is possible to comment on any bias that may be introduced by exclusions.

Response: We disagree with the commenter's suggestion that we should provide the numerators and denominators for the calculation as we do not believe this would allow commenters to determine whether any bias may be introduced by exclusions. Rather, we believe that the detailed description of the data (specifically the Medicare cost report worksheet fields) and trimming methodologies allow the commenter to evaluate the bias. Specifically, commenters are able to evaluate the accuracy and reasonableness of the Medicare cost report worksheet fields. They are also able to replicate the results and then compare the trimmed cost share weight samples to the national average distribution of total costs. We reiterate that in deriving the proposed SNF cost weights, we used a similar trimming methodology for each of the major cost weights, with the exception of the Home Office Contract Labor cost weight as discussed earlier in this final rule (as we explained, for the Home Office Contract Labor cost weight, we used an alternative methodology). Our review of the trimmed samples for each of the major cost weights (Wages and Salaries, Employee Benefits, Contract Labor, Professional Liability, Home Office Contract Labor, Pharmaceuticals and Capital) resulted in a total cost distribution that was similar to the cost distribution of the untrimmed sample when compared by urban/rural status, ownership-type (for-profit, nonprofit, or government) and then by census region. We would further note that, as stated above, the trimming of the individual cost weights was done independently of each other, in an effort to produce the most representative data for each of the major cost weights. Finally, we would note that the 5 percent trim is the same methodology used to derive cost share weights (with the exception of the Home Office Contract Labor cost weight) for other CMS market baskets.

Comment: One commenter questioned whether it is time to possibly make some revisions to Worksheet A of the Medicare SNF cost report. They provided suggested additional cost categories that they believe would help construct a more accurate market basket and to account for regional fluctuations (for example, utility costs, property insurance rates, etc).

Response: The commenter's specific detailed recommendations for changes to the Medicare cost report are outside the scope of the FY 2018 SNF PPS proposed rule. However, we appreciate and will consider the commenter's suggestion to capture additional information on the SNF Medicare cost report for possible future use in the SNF market basket.

Comment: One commenter had several questions on the methodology used to develop the major cost weights of the 2014-based SNF market basket. The commenter specifically questioned our trimming methods and whether we excluded partial-year cost reports (that is, providers with cost report data of less than 12 months). They also stated there was no information provided regarding the treatment of missing data in the cost report fields and that zero and missing data do not have the same meaning. They further stated that missing data was high for certain weights with over 40 percent of cost reports having missing values for professional liability insurance, over 70 percent of cost reports having missing values in home office contract labor costs, and over 80 percent having missing values in the Pharmacy cost center used to determine the Pharmaceuticals cost weight.

Response: We appreciate the commenter's review of the methodology used to develop the 2014-based SNF market basket. We made no edits to remove providers with partial cost reporting periods and, therefore, they were included in the initial set of cost reports. In response to this comment, we examined the impact of excluding those providers that reported costs for a period of fewer than 270 days (representing about ¾ of the cost reporting year) and, similar to the commenter's finding, found that its impact on the major cost weights was minimal with less than 0.1 percentage point in absolute terms. Given its small impact, we do not believe it is necessary to revise the 2014-based SNF market basket to reflect the exclusion of reports with a partial cost reporting period; however, we will consider the merits of this edit for future rebasings.

In regards to the commenter's request for information on the treatment of missing data in the cost report fields, CMS receives Medicare cost report data via the Electronic Cost Reporting file from the Medicare Administrative Contractor. These files do not have missing values for numeric fields; therefore, fields are zero or greater. The

public-use files provided on the CMS Web site, however, convert the zero values to missing or null.

We recognize the commenter's concern of providers' reporting zero Professional Liability and Pharmaceutical costs. As stated, in the FY 2018 SNF PPS proposed rule (82 FR 21030), for each of the major cost weights, except for Home Office Contract Labor as discussed above, (that is (Wages and Salaries, Employee Benefits, Contract Labor, Pharmaceuticals, Professional Liability Insurance, Home Office Contract Labor, and Capital-related Expenses) the data were trimmed to remove outliers (a standard statistical process) by first requiring that major expenses and total Medicare-allowable costs are greater than zero. For these major cost weights (Wages and Salaries, Employee Benefits, Contract Labor, Professional Liability, Capital and Pharmaceuticals), we believe that providers should incur these expenses to provide SNF services to beneficiaries. Therefore, cost reports with zero costs for major expenses (except Home Office Contract Labor costs) were excluded from the market basket cost weight calculation before trimming the top and bottom five percent. We note, as stated in the proposed rule, the trimming method is done for each cost weight individually and, therefore, providers excluded from one cost weight calculation are not automatically excluded from other cost weight calculations. This methodology allows us to use the largest possible sample of providers that report expenses for any given category.

However, as discussed earlier, we do not believe, as the Medicare cost report data (Worksheet S2, line 45) indicates, that all SNF providers will have a Home Office and then will also ''purchase'' services from their home office. Rather, providers can incur these expenses directly by having their own staff, for which the costs would be included in the Wages and Salaries and Benefits cost weights, or be purchased from contractors that are not directly affiliated with SNF, for which these expenses would be captured in the residual ''All-Other'' cost weight. Therefore, as discussed above, for the Home Office Contract Labor cost weight, we instead applied a one percent top trimming methodology but allowed all providers' Medicare-allowable costs to be included, even if their home office contract labor costs were zero.

Also, we included all data for subcategories of the major cost weights, except Home Office Contract Labor costs, (such as excluded area salaries component of the Wages and Salaries costs) even if they are zero as we believe it is reasonable for some of these specific costs to not be applicable to some providers. We must rely on the data that are submitted by providers and always encourage providers to fill out the cost report forms using the most accurate and complete data available to them.

Comment: One commenter made note of their inability to replicate all of the proposed cost weights using the methodology provided in the proposed rule. Specifically, the commenter was unable to replicate the Contract Labor cost weight and Home Office Contract Labor cost weight.

Response: We appreciate the commenter's review of our methodology and their replication efforts. We note that in the FY 2018 SNF PPS proposed rule, we made an error in the description of which Medicare cost report line is used to determine the Medicare allowable contract labor costs. The proposed rule stated that Medicare allowable contract labor costs would be equal to Worksheet S–3, part II, column 3, line 17, which reflects costs for contracted direct patient care services, that is, nursing, therapeutic, rehabilitative, or diagnostic services furnished under contract, rather than by employees and management contract services. These Medicare allowable contract labor costs are actually reported in Worksheet S–3, part II, column 3, line 14 as per the CMS Form 2540–10 instructions. We note that the processing of the data was correct, and we appropriately used Worksheet S–3, part II, column 3, line 14, but our written description of the line used was not. We apologize for any confusion and have corrected this typographical error in this final rule.

As stated above, in the FY 2018 SNF PPS proposed rule, we mistakenly indicated that we used the same trimming methodology for the Home Office Contract Labor cost weight that we used for the other major cost weights (a top and bottom five percent trimming method). For the Home Office Contract Labor cost weight we applied a one percent top-only trimming methodology. This trimming methodology allowed all providers' Medicare-allowable costs to be included, even if their home office contract labor costs were zero. We believe this one percent trimming methodology is appropriate for the Home Office Contract Labor cost weight as it addresses outliers while allowing providers with zero Home Office Contract Labor costs to be included in the Home Office Contract Labor cost weight calculation. Applying a five percent top and bottom trimming methodology would exclude providers who have zero Home Office Contract Labor costs.

After consideration of the public comments we received, for the reasons discussed above and in the FY 2018 SNF PPS proposed rule, we are finalizing the major cost weights as proposed, without modification. Table 9 below shows the major cost categories and their respective cost weights as derived from the Medicare cost reports for this final rule.

TABLE 9—MAJOR COST CATEGORIES AS DERIVED FROM THE MEDICARE COST REPORTS

Major cost categories	Final 2014-based	FY 2010-based
Wages and Salaries	44.3	46.1
Employee Benefits	9.3	10.5
Contract Labor	6.8	5.5
Pharmaceuticals	7.3	7.9
Professional Liability Insurance	1.1	1.1
Home Office Contract Labor*	0.7	n/a
Capital-related	7.9	7.4
All other (residual)	22.6	21.5

* Home office contract labor costs were included in the residual ''All Other'' cost weight of the FY 2010-based SNF market basket.

The Wages and Salaries and Employee Benefits cost weights as calculated directly from the Medicare cost reports decreased by 1.8 and 1.2 percentage points, respectively, while the Contract Labor cost weight increased 1.3 percentage points between the FY 2010-based SNF market basket and 2014-based SNF market basket. The decrease in the Wages and Salaries occurred among most cost centers and in aggregate for the General Service (overhead) and Inpatient Routine Service cost centers, which together account for about 80 percent of total facility costs.

As we did for the FY 2010-based SNF market basket (78 FR 26452), we proposed to allocate contract labor costs to the Wages and Salaries and Employee Benefits cost weights based on their relative proportions under the assumption that contract labor costs are comprised of both wages and salaries and employee benefits. The contract labor allocation proportion for wages and salaries is equal to the Wages and Salaries cost weight as a percent of the sum of the Wages and Salaries cost weight and the Employee Benefits cost weight. Using the 2014 Medicare cost report data, this percentage is 83 percent; therefore, we proposed to allocate approximately 83 percent of the Contract Labor cost weight to the Wages and Salaries cost weight and 17 percent to the Employee Benefits cost weight. For the FY 2010-based SNF market basket, the wages and salaries to employee benefit ratio was 81/19 percent.

We did not receive public comments on our proposed allocation of contract labor costs to Wages and Salaries and Employee Benefits. For the reasons discussed above and in the FY 2018 SNF PPS proposed rule, we are finalizing the allocation methodology and percentages as proposed, without modification. Table 10 below shows the Wages and Salaries and Employee Benefits cost weights after contract labor allocation for the FY 2010-based SNF market basket and the 2014-based SNF market basket.

TABLE 10—WAGES AND SALARIES AND EMPLOYEE BENEFITS COST WEIGHTS AFTER CONTRACT LABOR ALLOCATION

Major cost categories	Final 2014-based market basket	FY 2010-based market basket
Wages and Salaries	50.0	50.6
Employee Benefits	10.5	11.5

ii. Derivation of the Detailed Operating Cost Weights

To further divide the ''All Other'' residual cost weight estimated from the 2014 Medicare cost report data into more detailed cost categories, we proposed to use the 2007 Benchmark I–O ''Use Tables/Before Redefinitions/Purchaser Value'' for Nursing and Community Care Facilities industry (NAICS 623A00), published by the Census Bureau's Bureau of Economic Analysis (BEA). These data are publicly available at the following Web site: *http://www.bea.gov/industry/io_annual.htm.* The BEA Benchmark I–O data are generally scheduled for publication every 5 years with the most recent data available for 2007. The 2007 Benchmark I–O data are derived from the 2007 Economic Census and are the building blocks for BEA's economic accounts. Therefore, they represent the most comprehensive and complete set of data on the economic processes or mechanisms by which output is produced and distributed.[2] BEA also produces Annual I–O estimates. However, while based on a similar methodology, these estimates reflect less comprehensive and less detailed data sources and are subject to revision when benchmark data become available. Instead of using the less detailed Annual I–O data, we proposed to inflate the 2007 Benchmark I–O data aged forward to 2014 by applying the annual price changes from the respective price proxies to the appropriate market basket cost categories that are obtained from the 2007 Benchmark I–O data. We repeated this practice for each year. We then calculated the cost shares that each cost category represents of the 2007 data inflated to 2014. These resulting 2014 cost shares were applied to the ''All Other'' residual cost weight to obtain the detailed cost weights for the proposed 2014-based SNF market basket. For example, the cost for Food: Direct Purchases represents 13.7 percent of the sum of the ''All Other'' 2007 Benchmark I–O Expenditures inflated to 2014. Therefore, the Food: Direct Purchases cost weight represents 3.1 percent of the proposed 2014-based SNF market basket's ''All Other'' cost category (0.137 × 22.6 percent = 3.1 percent). For the FY 2010-based SNF market basket (78 FR 26456), we used the same methodology utilizing the 2002 Benchmark I–O data (aged to FY 2010).

Using this methodology, we proposed to derive 21 detailed SNF market basket operating cost category weights from the proposed 2014-based SNF market basket ''All Other'' residual cost weight (22.6 percent). These categories are: (1) Fuel: Oil and Gas; (2) Electricity; (3) Water and Sewerage; (4) Food: Direct Purchases; (5) Food: Contract Services; (6) Chemicals; (7) Medical Instruments and Supplies; (8) Rubber and Plastics; (9) Paper and Printing Products; (10) Apparel; (11) Machinery and Equipment; (12) Miscellaneous Products; (13) Professional Fees: Labor-Related; (14) Administrative and Facilities Support Services; (15) Installation, Maintenance, and Repair Services; (16) All Other: Labor-Related Services; (17) Professional Fees: Nonlabor-Related; (18) Financial Services; (19) Telephone Services; (20) Postage; and (21) All Other: Nonlabor-Related Services.

We note that the machinery and equipment expenses are for equipment that is paid for in a given year and not depreciated over the asset's useful life. Depreciation expenses for movable equipment are reflected in the capital component of the proposed 2014-based SNF market basket (described in section V.A.1.c. of the proposed rule (82 FR 21032) and section III.D.1.c. of this final rule).

We would also note that for ease of reference we proposed to rename the Nonmedical Professional Fees: Labor-Related and Nonmedical Professional Fees: Nonlabor-related cost categories (as labeled in the FY 2010-based SNF market basket) to be Professional Fees: Labor-Related and Professional Fees: Nonlabor-Related in the 2014-based SNF market basket. These cost categories still represent the same nonmedical professional fees that were included in the FY 2010-based SNF

[2] *http://www.bea.gov/papers/pdf/IOmanual_092906.pdf.*

market basket, which we describe in section V.A.4. of the proposed rule (82 FR 21039) and section III.D.1.d. of this final rule.

For the 2014-based SNF market basket, we proposed to include a separate cost category for Installation, Maintenance, and Repair Services to proxy these costs by a price index that better reflects the price changes of labor associated with maintenance-related services. Previously these costs were included in the All Other: Labor-Related Services category of the FY 2010-based SNF market basket.

Provided below are summaries of the comments we received regarding the derivation of the detailed operating cost weights, as well as our responses.

Comment: Several commenters believe a SNF cost distribution study from 2007 is out-of-date and not likely to represent the distribution of cost in 2014 or going forward. For example, according to the commenter, operational changes driven by the Requirements of Participation will have substantial impacts. The commenter stated that the function of a market basket is to update SNF payment based on real changes in cost over time. The commenter claimed that the use of a static 2007 study is inconsistent with the fundamental intent of the market basket. The commenter requested information regarding how CMS could gather more current data on SNF costs.

Response: To further divide the ''All Other'' residual cost weight of 22.6 percent into more detailed cost categories, we proposed to use the 2007 Benchmark I–O for Nursing and Community Care Facilities industry (NAICS 623A00). For each of the detailed expenses (such as food: Direct purchase), we inflate the 2007 expense to 2014 using the relevant price proxies. The resulting 2014 cost shares based on these inflated expenses were applied to the ''All Other'' residual cost weight to obtain the detailed cost weights for the 2014-based SNF market basket.

Thus, our methodology does in fact reflect changes in expenses from 2007 to 2014, but is based on the assumption that the change in quantities over this period is equal to the change in prices. We believe this is a reasonable assumption as it is consistent with historical data which shows the cost shares changing over time. We believe this is a better methodology for developing the market basket rather than keeping the shares fixed between 2007 and 2014 or proxying the ''All Other'' residual by an aggregate index such as the CPI All-Items, which would not reflect the unique cost structures of SNFs.

It is not until late 2018, when BEA is expected to release 2012 Benchmark I–O data, that we will be able to determine whether the growth in quantities for these specific costs grew similarly to prices over this period, as we currently assume in the market basket. We will evaluate these data and consider its inclusion for the development of the SNF market basket in the future.

After consideration of the public comments we received, for the reasons discussed above and in the FY 2018 SNF PPS proposed rule, we are finalizing the detailed operating cost weights and methodology for deriving such weights as proposed, without modification.

iii. Derivation of the Detailed Capital Cost Weights

Similar to the FY 2010-based SNF market basket, we proposed to further divide the Capital-related cost weight into: Depreciation, Interest, Lease and Other Capital-related cost weights.

We proposed to calculate the depreciation cost weight (that is, depreciation costs excluding leasing costs) using depreciation costs from Worksheet S–2, column 1, lines 20 and 21. Since the depreciation costs reflect the entire SNF facility (Medicare and non-Medicare-allowable units), we proposed to use total facility capital costs as the denominator. This methodology assumes that the depreciation of an asset is the same regardless of whether the asset was used for Medicare or non-Medicare patients. This methodology yielded depreciation as a percent of capital costs of 27.3 percent for 2014. We then applied this percentage to the proposed 2014-based SNF market basket Medicare-allowable Capital-related cost weight of 7.9 percent, yielding a Medicare-allowable depreciation cost weight (excluding leasing expenses, which is described in more detail below) of 2.2 percent. To further disaggregate the Medicare-allowable depreciation cost weight into fixed and moveable depreciation, we proposed to use the 2014 SNF MCR data for end-of-the-year capital asset balances as reported on Worksheet A7. The 2014 SNF MCR data showed a fixed/moveable split of 83/17. The FY 2010-based SNF market basket, which utilized the same data from the FY 2010 MCRs, had a fixed/moveable split of 85/15.

We also proposed to derive the interest expense share of capital-related expenses from 2014 SNF MCR data, specifically from Worksheet A, column 2, line 81. Similar to the depreciation cost weight, we proposed to calculate the interest cost weight using total facility capital costs. This methodology yielded interest as a percent of capital costs of 27.4 percent for 2014. We then applied this percentage to the proposed 2014-based SNF market basket Medicare-allowable Capital-related cost weight of 7.9 percent, yielding a Medicare-allowable interest cost weight (excluding leasing expenses) of 2.2 percent. As done with the last SNF market basket rebasing (78 FR 26454), we proposed to determine the split of interest expense between for-profit and not-for-profit facilities based on the distribution of long-term debt outstanding by type of SNF (for-profit or not-for-profit/government) from the 2014 SNF MCR data. We estimated the split between for-profit and not-for-profit interest expense to be 27/73 percent compared to the FY 2010-based SNF market basket with 41/59 percent.

Because the detailed data were not available in the MCRs, we proposed to use the most recent 2014 Census Bureau Service Annual Survey (SAS) data to derive the capital-related expenses attributable to leasing and other capital-related expenses. The FY 2010-based SNF market basket used the 2010 SAS data. Based on the 2014 SAS data, we determined that leasing expenses are 63 percent of total leasing and capital-related expenses costs. In the FY 2010-based SNF market basket, leasing costs represent 62 percent of total leasing and capital-related expenses costs. We then applied this percentage to the proposed 2014-based SNF market basket residual Medicare-allowable capital costs of 3.6 percent derived from subtracting the Medicare-allowable depreciation cost weight and Medicare-allowable interest cost weight from the 2014-based SNF market basket of total Medicare-allowable capital cost weight (7.9 percent − 2.2 percent − 2.2 percent = 3.6 percent). This produced the proposed 2014-based SNF Medicare-allowable leasing cost weight of 2.3 percent and all-other capital-related cost weight of 1.3 percent.

Lease expenses are not broken out as a separate cost category in the SNF market basket, but are distributed among the cost categories of depreciation, interest, and other capital-related expenses, reflecting the assumption that the underlying cost structure and price movement of leasing expenses is similar to capital costs in general. As was done with past SNF market baskets and other PPS market baskets, we assumed 10 percent of lease expenses are overhead and proposed to assign them to the other capital-related expenses cost category. This is based on the assumption that leasing expenses

include not only depreciation, interest, and other capital-related costs but also additional costs paid to the lessor. We distributed the remaining lease expenses to the three cost categories based on the proportion of depreciation, interest, and other capital-related expenses to total capital costs, excluding lease expenses.

We did not receive any public comments on our proposed methodology for deriving the detailed capital cost weights. Therefore, for the reasons discussed above and in the FY 2018 SNF PPS proposed rule, we are finalizing the detailed capital cost weights and methodology as proposed, without modification.

Table 11 shows the capital-related expense distribution (including expenses from leases) in the final 2014-based SNF market basket and the FY 2010-based SNF market basket.

TABLE 11—COMPARISON OF THE CAPITAL-RELATED EXPENSE DISTRIBUTION OF THE 2014-BASED SNF MARKET BASKET AND THE FY 2010-BASED SNF MARKET BASKET

Cost category	Final 2014-based SNF market basket	FY 2010-based SNF market basket
Capital-related Expenses	7.9	7.4
Total Depreciation	2.9	3.2
Total Interest	3.0	2.1
Other Capital-related Expenses	2.0	2.1

Note: The cost weights are calculated using three decimal places. For presentational purposes, we are displaying one decimal and therefore, the detail capital cost weights may not add to the total capital-related expenses cost weight due to rounding.

Table 12 presents the final 2014-based SNF market basket and the FY 2010-based SNF market basket.

TABLE 12—2014-BASED SNF MARKET BASKET AND FY 2010-BASED SNF MARKET BASKET

Cost category	Final 2014-based SNF market basket	FY 2010-based SNF market basket
Total	100.0	100.0
Compensation	60.4	62.1
Wages and Salaries [1]	50.0	50.6
Employee Benefits [1]	10.5	11.5
Utilities	2.6	2.2
Electricity	1.2	1.4
Fuel: Oil and Gas	1.3	0.7
Water and Sewerage	0.2	0.1
Professional Liability Insurance	1.1	1.1
All Other	27.9	27.2
Other Products	14.3	16.1
Pharmaceuticals	7.3	7.9
Food: Direct Purchase	3.1	3.7
Food: Contract Purchase	0.7	1.2
Chemicals	0.2	0.2
Medical Instruments and Supplies	0.6	0.8
Rubber and Plastics	0.8	1.0
Paper and Printing Products	0.8	0.8
Apparel	0.3	0.2
Machinery and Equipment	0.3	0.2
Miscellaneous Products	0.3	0.3
All Other Services	13.6	11.0
Labor-Related Services	7.4	6.2
Professional Fees: Labor-related	3.8	3.4
Installation, Maintenance, and Repair Services	0.6	n/a
Administrative and Facilities Support	0.5	0.5
All Other: Labor-Related Services	2.5	2.3
Non Labor-Related Services	6.2	4.8
Professional Fees: Nonlabor-Related	1.8	2.0
Financial Services	2.0	0.9
Telephone Services	0.5	0.6
Postage	0.2	0.2
All Other: Nonlabor-Related Services	1.8	1.1
Capital-Related Expenses	7.9	7.4
Total Depreciation	2.9	3.2
Building and Fixed Equipment	2.5	2.7
Movable Equipment	0.4	0.5
Total Interest	3.0	2.1
For-Profit SNFs	0.8	0.9

TABLE 12—2014-BASED SNF MARKET BASKET AND FY 2010-BASED SNF MARKET BASKET—Continued

Cost category	Final 2014-based SNF market basket	FY 2010-based SNF market basket
Government and Nonprofit SNFs	2.1	1.2
Other Capital-Related Expenses	2.0	2.1

Note: The cost weights are calculated using three decimal places. For presentational purposes, we are displaying one decimal and therefore, the detailed cost weights may not add to the aggregate cost weights or to 100.0 due to rounding.

[1] Contract labor is distributed to wages and salaries and employee benefits based on the share of total compensation that each category represents.

b. Price Proxies Used To Measure Operating Cost Category Growth

After developing the 30 cost weights for the 2014-based SNF market basket, we selected the most appropriate wage and price proxies currently available to represent the rate of change for each expenditure category. With four exceptions (three for the capital-related expenses cost categories and one for Professional Liability Insurance (PLI)), we base the wage and price proxies on Bureau of Labor Statistics (BLS) data, and group them into one of the following BLS categories:

- *Employment Cost Indexes:* Employment Cost Indexes (ECIs) measure the rate of change in employment wage rates and employer costs for employee benefits per hour worked. These indexes are fixed-weight indexes and strictly measure the change in wage rates and employee benefits per hour. ECIs are superior to Average Hourly Earnings (AHE) as price proxies for input price indexes because they are not affected by shifts in occupation or industry mix, and because they measure pure price change and are available by both occupational group and by industry. The industry ECIs are based on the 2004 North American Classification System (NAICS).
- *Producer Price Indexes:* Producer Price Indexes (PPIs) measure price changes for goods sold in other than retail markets. PPIs are used when the purchases of goods or services are made at the wholesale level.
- *Consumer Price Indexes:* Consumer Price Indexes (CPIs) measure change in the prices of final goods and services bought by consumers. CPIs are only used when the purchases are similar to those of retail consumers rather than purchases at the wholesale level, or if no appropriate PPI were available.

We evaluated the price proxies using the criteria of reliability, timeliness, availability, and relevance. Reliability indicates that the index is based on valid statistical methods and has low sampling variability. Widely accepted statistical methods ensure that the data were collected and aggregated in a way that can be replicated. Low sampling variability is desirable because it indicates that the sample reflects the typical members of the population. (Sampling variability is variation that occurs by chance because only a sample was surveyed rather than the entire population.) Timeliness implies that the proxy is published regularly, preferably at least once a quarter. The market baskets are updated quarterly, and therefore, it is important for the underlying price proxies to be up-to-date, reflecting the most recent data available. We believe that using proxies that are published regularly (at least quarterly, whenever possible) helps to ensure that we are using the most recent data available to update the market basket. We strive to use publications that are disseminated frequently, because we believe that this is an optimal way to stay abreast of the most current data available. Availability means that the proxy is publicly available. We prefer that our proxies are publicly available because this will help ensure that our market basket updates are as transparent to the public as possible. In addition, this enables the public to be able to obtain the price proxy data on a regular basis. Finally, relevance means that the proxy is applicable and representative of the cost category weight to which it is applied. The CPIs, PPIs, and ECIs that we have selected to propose in this regulation meet these criteria. Therefore, we believe that they continue to be the best measure of price changes for the cost categories to which they would be applied.

Table 15 in the proposed rule (82 FR 21039) lists all price proxies for the 2014-based SNF market basket. Below is a detailed explanation of the proposed price proxies used for each operating cost category.

- *Wages and Salaries:* We proposed to use the ECI for Wages and Salaries for Private Industry Workers in Nursing Care Facilities (NAICS 6231; BLS series code CIU2026231000000I) to measure price growth of this category. NAICS 623 includes facilities that provide a mix of health and social services, with many of the health services being largely some level of nursing services. Within NAICS 623 is NAICS 6231, which includes nursing care facilities primarily engaged in providing inpatient nursing and rehabilitative services. These facilities, which are most comparable to Medicare-certified SNFs, provide skilled nursing and continuous personal care services for an extended period of time, and, therefore, have a permanent core staff of registered or licensed practical nurses. This is the same index used in the FY 2010-based SNF market basket.
- *Employee Benefits:* We proposed to use the ECI for Benefits for Nursing Care Facilities (NAICS 6231) to measure price growth of this category. The ECI for Benefits for Nursing Care Facilities is calculated using BLS's total compensation (BLS series ID CIU2016231000000I) for nursing care facilities series and the relative importance of wages and salaries within total compensation. We believe this constructed ECI series is technically appropriate for the reason stated above in the Wages and Salaries price proxy section. This is the same index used in the FY 2010-based SNF market basket.
- *Electricity:* We proposed to use the PPI Commodity for Commercial Electric Power (BLS series code WPU0542) to measure the price growth of this cost category. This is the same index used in the FY 2010-based SNF market basket.
- *Fuel: Oil and Gas:* We proposed to change the proxy used for the Fuel: Oil and Gas cost category. The FY 2010-based SNF market basket uses the PPI Commodity for Commercial Natural Gas (BLS series code WPU0552) to proxy these expenses. For the 2014-based SNF market basket, we proposed to use a blend of the PPI Industry for Petroleum Refineries (BLS series code PCU32411–32411) and the PPI Commodity for Natural Gas (BLS series code WPU0531). Our analysis of the Bureau of Economic Analysis' 2007 Benchmark I–O data for Nursing and Community Care Facilities shows that petroleum refineries expenses accounts for

approximately 65 percent and natural gas accounts for approximately 35 percent of the fuel: Oil and gas expenses. Therefore, we proposed a blended proxy of 65 percent of the PPI Industry for Petroleum Refineries (BLS series code PCU32411–32411) and 35 percent of the PPI Commodity for Natural Gas (BLS series code WPU0531). We believe that these two price proxies are the most technically appropriate indices available to measure the price growth of the Fuel: Oil and Gas category in the 2014-based SNF market basket.

• *Water and Sewerage:* We proposed to use the CPI All Urban for Water and Sewerage Maintenance (BLS series code CUUR0000SEHG01) to measure the price growth of this cost category. This is the same index used in the FY 2010-based SNF market basket.

• *Professional Liability Insurance:* We proposed to use the CMS Hospital Professional Liability Insurance Index to measure price growth of this category. We were unable to find a reliable data source that collects SNF-specific PLI data. Therefore, we proposed to use the CMS Hospital Professional Liability Index, which tracks price changes for commercial insurance premiums for a fixed level of coverage, holding non-price factors constant (such as a change in the level of coverage). This is the same index used in the FY 2010-based SNF market basket. We believe this is an appropriate proxy to measure the price growth associated of SNF professional liability insurance as it captures the price inflation associated with other medical institutions that serve Medicare patients.

• *Pharmaceuticals:* We proposed to use the PPI Commodity for Pharmaceuticals for Human Use, Prescription (BLS series code WPUSI07003) to measure the price growth of this cost category. This is the same index used in the FY 2010-based SNF market basket.

• *Food: Wholesale Purchases:* We proposed to use the PPI Commodity for Processed Foods and Feeds (BLS series code WPU02) to measure the price growth of this cost category. This is the same index used in the FY 2010-based SNF market basket.

• *Food: Retail Purchase:* We proposed to use the CPI All Urban for Food Away From Home (All Urban Consumers) (BLS series code CUUR0000SEFV) to measure the price growth of this cost category. This is the same index used in the FY 2010-based SNF market basket.

• *Chemicals:* For measuring price change in the Chemicals cost category, we proposed to use a blended PPI composed of the Industry PPIs for Other Basic Organic Chemical Manufacturing (NAICS 325190) (BLS series code PCU32519–32519), Soap and Cleaning Compound Manufacturing (NAICS 325610) (BLS series code PCU32561–32561), and Other Miscellaneous Chemical Product Manufacturing (NAICS 3259A0) (BLS series code PCU325998325998).

Using the 2007 Benchmark I–O data, we found that these three NAICS industries accounted for approximately 96 percent of SNF chemical expenses. The remaining four percent of SNF chemical expenses are for three other incidental NAICS chemicals industries such as Paint and Coating Manufacturing. We proposed to create a blended index based on those three NAICS chemical expenses listed above that account for 96 percent of SNF chemical expenses. We proposed to create this blend based on each NAICS' expenses as a share of their sum. These expenses as a share of their sum are listed in Table 34.

The FY 2010-based SNF market basket also used a blended chemical proxy that was based on 2002 Benchmark I–O data. We believe our proposed chemical blended index for the 2014-based SNF market basket is technically appropriate as it reflects more recent data on SNFs purchasing patterns. Table 13 in the proposed rule (82 FR 21035) provided the weights for the 2014-based blended chemical index and the FY 2010-based blended chemical index. The table is also shown below.

TABLE 13—PROPOSED CHEMICAL BLENDED INDEX WEIGHTS

NAICS	Industry description	2014-based index (%)	2010-based index (%)
325190	Other basic organic chemical manufacturing	22	7
25510	Paint and coating manufacturing	n/a	12
325610	Soap and cleaning compound manufacturing	37	49
3259A0	Other miscellaneous chemical product manufacturing	41	32
Total		100	100

As discussed below, we are finalizing the weights for the 2014-based blended chemical index as proposed, without modification.

• *Medical Instruments and Supplies:* We proposed to use a blend for the Medical Instruments and Supplies cost category. The 2007 Benchmark I–O data shows an approximate 60/40 split between 'Medical and Surgical Appliances and Supplies' and 'Surgical and Medical Instruments'. Therefore, we proposed a blend composed of 60 percent of the PPI Commodity for Medical and Surgical Appliances and Supplies (BLS series code WPU1563) and 40 percent of the PPI Commodity for Surgical and Medical Instruments (BLS series code WPU1562).

The FY 2010-based SNF market basket used the single, higher level PPI Commodity for Medical, Surgical, and Personal Aid Devices (BLS series code WPU156). We believe that the proposed price proxy better reflects the mix of expenses for this cost category as obtained from the 2007 Benchmark I–O data.

• *Rubber and Plastics:* We proposed to use the PPI Commodity for Rubber and Plastic Products (BLS series code WPU07) to measure price growth of this cost category. This is the same index used in the FY 2010-based SNF market basket.

• *Paper and Printing Products:* We proposed to use the PPI Commodity for Converted Paper and Paperboard Products (BLS series code WPU0915) to measure the price growth of this cost category. This is the same index used in the FY 2010-based SNF market basket.

• *Apparel:* We proposed to use the PPI Commodity for Apparel (BLS series code WPU0381) to measure the price growth of this cost category. This is the same index used in the FY 2010-based SNF market basket.

• *Machinery and Equipment:* We proposed to use the PPI Commodity for Machinery and Equipment (BLS series code WPU11) to measure the price growth of this cost category. This is the

same index used in the FY 2010-based SNF market basket.

• *Miscellaneous Products:* For measuring price change in the Miscellaneous Products cost category, we proposed to use the PPI Commodity for Finished Goods less Food and Energy (BLS series code WPUFD4131). Both food and energy are already adequately represented in separate cost categories and should not also be reflected in this cost category. This is the same index used in the FY 2010-based SNF market basket.

• *Professional Fees: Labor-Related:* We proposed to use the ECI for Total Compensation for Private Industry Workers in Professional and Related (BLS series code CIU2010000120000I) to measure the price growth of this category. This is the same index used in the FY 2010-based SNF market basket (which was called the Nonmedical Professional Fees: Labor-Related cost category).

• *Administrative and Facilities Support Services:* We proposed to use the ECI for Total Compensation for Private Industry Workers in Office and Administrative Support (BLS series code CIU2010000220000I) to measure the price growth of this category. This is the same index used in the FY 2010-based SNF market basket.

• *Installation, Maintenance and Repair Services:* We proposed to include a separate cost category for Installation, Maintenance, and Repair Services to proxy these costs by a price index that better reflects the price changes of labor associated with maintenance-related services. We proposed to use the ECI for Total Compensation for All Civilian Workers in Installation, Maintenance, and Repair (BLS series code CIU1010000430000I) to measure the price growth of this new cost category. Previously these costs were included in the All Other: Labor-Related Services category and were proxied by the ECI for Total Compensation for Private Industry Workers in Service Occupations (BLS series code CIU2010000300000I).

• *All Other: Labor-Related Services:* We proposed to use the ECI for Total Compensation for Private Industry Workers in Service Occupations (BLS series code CIU2010000300000I) to measure the price growth of this cost category. This is the same index used in the FY 2010-based SNF market basket.

• *Professional Fees: NonLabor-Related:* We proposed to use the ECI for Total Compensation for Private Industry Workers in Professional and Related (BLS series code CIU2010000120000I) to measure the price growth of this category. This is the same index used in the FY 2010-based SNF market basket (which was called the Nonmedical Professional Fees: Nonlabor-Related cost category).

• *Financial Services:* We proposed to use the ECI for Total Compensation for Private Industry Workers in Financial Activities (BLS series code CIU201520A000000I) to measure the price growth of this cost category. This is the same index used in the FY 2010-based SNF market basket.

• *Telephone Services:* We proposed to use the CPI All Urban for Telephone Services (BLS series code CUUR0000SEED) to measure the price growth of this cost category. This is the same index used in the FY 2010-based SNF market basket.

• *Postage:* We proposed to use the CPI All Urban for Postage (BLS series code CUUR0000SEEC) to measure the price growth of this cost category. This is the same index used in the FY 2010-based SNF market basket.

• *All Other: NonLabor-Related Services:* We proposed to use the CPI All Urban for All Items Less Food and Energy (BLS series code CUUR0000SA0L1E) to measure the price growth of this cost category. This is the same index used in the FY 2010-based SNF market basket.

We did not receive any public comments on our proposed price proxies for each of the operating cost categories. For the reasons discussed above and in the FY 2018 SNF PPS proposed rule, we are finalizing the price proxies of the operating cost categories as proposed, without modification. In addition, we did not receive any public comments on our proposed weights for the 2014-based blended chemical index. Thus, for the reasons discussed above and in the FY 2018 SNF PPS proposed rule, we are finalizing the weights for 2014-based blended chemical index as proposed, without modification.

c. Price Proxies Used To Measure Capital Cost Category Growth

We proposed to apply the same price proxies as were used in the FY 2010-based SNF market basket, and below is a detailed explanation of the price proxies used for each capital cost category. We also proposed to continue to vintage weight the capital price proxies for Depreciation and Interest to capture the long-term consumption of capital. This vintage weighting method is the same method that was used for the FY 2010-based SNF market basket and is described below.

• *Depreciation—Building and Fixed Equipment:* We proposed to use the BEA Chained Price Index for Private Fixed Investment in Structures, Nonresidential, Hospitals and Special Care (BEA Table 5.4.4. Price Indexes for Private Fixed Investment in Structures by Type). This BEA index is intended to capture prices for construction of facilities such as hospitals, nursing homes, hospices, and rehabilitation centers.

• *Depreciation—Movable Equipment:* We proposed to use the PPI Commodity for Machinery and Equipment (BLS series code WPU11). This price index reflects price inflation associated with a variety of machinery and equipment that would be utilized by SNFs including but not limited to medical equipment, communication equipment, and computers.

• *Nonprofit Interest:* We proposed to use the average yield on Municipal Bonds (Bond Buyer 20-bond index).

• *For-Profit Interest:* We proposed to use the average yield on Moody's AAA corporate bonds (Federal Reserve). We proposed different proxies for the interest categories because we believe interest price pressures differ between nonprofit and for-profit facilities.

• *Other Capital:* Since this category includes fees for insurances, taxes, and other capital-related costs, we proposed to use the CPI All Urban for Owners' Equivalent Rent of Primary Residence (BLS series code CUUR0000SEHC01), which would reflect the price growth of these costs.

We believe that these price proxies continue to be the most appropriate proxies for SNF capital costs that meet our selection criteria of relevance, timeliness, availability, and reliability.

As stated above, we proposed to continue to vintage weight the capital price proxies for Depreciation and Interest to capture the long-term consumption of capital. To capture the long-term nature, the price proxies are vintage-weighted; and the vintage weights are calculated using a two-step process. First, we determined the expected useful life of capital and debt instruments held by SNFs. Second, we identified the proportion of expenditures within a cost category that is attributable to each individual year over the useful life of the relevant capital assets, or the vintage weights.

We proposed to rely on Bureau of Economic Analysis (BEA) fixed asset data to derive the useful lives of both fixed and movable capital, which is the same data source used to derive the useful lives for the FY 2010-based SNF market basket. The specifics of the data sources used are explained below.

i. Calculating Useful Lives for Moveable and Fixed Assets

Estimates of useful lives for movable and fixed assets for the 2014-based SNF market basket are 10 and 23 years, respectively. These estimates are based on three data sources from the BEA: (1) Current-cost average age; (2) historical-cost average age; and (3) industry-specific current cost net stocks of assets.

BEA current-cost and historical-cost average age data by asset type are not available by industry but are published at the aggregate level for all industries. The BEA does publish current-cost net capital stocks at the detailed asset level for specific industries. There are 61 detailed movable assets (including intellectual property) and there are 32 detailed fixed assets in the BEA estimates. Since we seek aggregate useful life estimates applicable to SNFs, we developed a methodology to approximate movable and fixed asset ages for nursing and residential care services (NAICS 623) using the published BEA data. For the proposed FY 2014 SNF market basket, we used the current-cost average age for each asset type from the BEA fixed assets Table 2.9 for all assets and weight them using current-cost net stock levels for each of these asset types in the nursing and residential care services industry, NAICS 6230. (For example, nonelectro medical equipment current-cost net stock (accounting for about 37 percent of total moveable equipment current-cost net stock in 2014) is multiplied by an average age of 4.7 years. Current-cost net stock levels are available for download from the BEA Web site at *http://www.bea.gov/national/FA2004/Details/Index.html.* We then aggregated the ''weighted'' current-cost net stock levels (average age multiplied by current-cost net stock) into moveable and fixed assets for NAICS 6230. We then adjusted the average ages for moveable and fixed assets by the ratio of historical-cost average age (Table 2.10) to current-cost average age (Table 2.9).

This produced historical cost average age data for movable (equipment and intellectual property) and fixed (structures) assets specific to NAICS 6230 of 4.8 and 11.6 years, respectively. The average age reflects the average age of an asset at a given point in time, whereas we want to estimate a useful life of the asset, which would reflect the average over all periods an asset is used. To do this, we multiplied each of the average age estimates by two to convert to average useful lives with the assumption that the average age is normally distributed (about half of the assets are below the average at a given point in time, and half above the average at a given point in time). This produced estimates of likely useful lives of 9.6 and 23.2 years for movable and fixed assets, which we rounded to 10 and 23 years, respectively. We proposed an interest vintage weight time span of 21 years, obtained by weighting the fixed and movable vintage weights (23 years and 10 years, respectively) by the fixed and movable split (87 percent and 13 percent, respectively). This is the same methodology used for the FY 2010-based SNF market basket which had useful lives of 22 years and 6 years for fixed and moveable assets, respectively. The impact of revising the useful life for moveable assets from 6 years to 10 years had little to no impact on the growth rate of the 2014-based SNF market basket capital cost weight. Over the 2014 to 2026 time period, the impact on the growth rate of the capital cost weight was no larger than 0.01 percent in absolute terms.

ii. Constructing Vintage Weights

Given the expected useful life of capital (fixed and moveable assets) and debt instruments, we then must determine the proportion of capital expenditures attributable to each year of the expected useful life for each of the three asset types: Building and fixed equipment, moveable equipment, and interest. These proportions represent the vintage weights. We were not able to find a historical time series of capital expenditures by SNFs. Therefore, we proposed to approximate the capital expenditure patterns of SNFs over time, using alternative SNF data sources. For building and fixed equipment, we used the stock of beds in nursing homes from the National Nursing Home Survey (NNHS) conducted by the National Center for Health Statistics (NCHS) for 1962 through 1999. For 2000 through 2010, we extrapolated the 1999 bed data forward using a 5-year moving average of growth in the number of beds from the SNF MCR data. For 2011 to 2014, we proposed to extrapolate the 2010 bed data forward using the average growth in the number of beds over the 2011 to 2014 time period. We then used the change in the stock of beds each year to approximate building and fixed equipment purchases for that year. This procedure assumes that bed growth reflects the growth in capital-related costs in SNFs for building and fixed equipment. We believe that this assumption is reasonable because the number of beds reflects the size of a SNF, and as a SNF adds beds, it also likely adds fixed capital.

As was done for the FY 2010-based SNF market basket (as well as prior market baskets), we proposed to estimate moveable equipment purchases based on the ratio of ancillary costs to routine costs. The time series of the ratio of ancillary costs to routine costs for SNFs measures changes in intensity in SNF services, which are assumed to be associated with movable equipment purchase patterns. The assumption here is that as ancillary costs increase compared to routine costs, the SNF caseload becomes more complex and would require more movable equipment. The lack of movable equipment purchase data for SNFs over time required us to use alternative SNF data sources. A more detailed discussion of this methodology was published in the FY 2008 SNF final rule (72 FR 43428). We believe the resulting two time series, determined from beds and the ratio of ancillary to routine costs, reflect real capital purchases of building and fixed equipment and movable equipment over time.

To obtain nominal purchases, which are used to determine the vintage weights for interest, we converted the two real capital purchase series from 1963 through 2014 determined above to nominal capital purchase series using their respective price proxies (the BEA Chained Price Index for Nonresidential Construction for Hospitals & Special Care Facilities and the PPI for Machinery and Equipment). We then combined the two nominal series into one nominal capital purchase series for 1963 through 2014. Nominal capital purchases are needed for interest vintage weights to capture the value of debt instruments.

Once we created these capital purchase time series for 1963 through 2014, we averaged different periods to obtain an average capital purchase pattern over time: (1) For building and fixed equipment, we averaged 30, 23-year periods; (2) for movable equipment, we averaged 43, 10-year periods; and (3) for interest, we averaged 32, 21-year periods. We calculate the vintage weight for a given year by dividing the capital purchase amount in any given year by the total amount of purchases during the expected useful life of the equipment or debt instrument. To provide greater transparency, we posted on the CMS market basket Web site at *http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/MedicareProgramRatesStats/MarketBasketResearch.html,* an illustrative spreadsheet that contains an example of how the vintage-weighted price indexes are calculated.

We did not receive any public comments on our proposed price proxies used for each of the detailed capital cost categories or on our methodology for deriving the vintage weights. For the reasons discussed above and in the FY 2018 SNF PPS proposed rule, we are finalizing the price proxies of the capital cost categories, the vintage weights, and the methodology for deriving the vintage weights, as proposed without modification.

The vintage weights for the 2014-based SNF market basket and the FY 2010-based SNF market basket are presented in Table 14.

TABLE 14—FINAL 2014-BASED VINTAGE WEIGHTS AND FY 2010-BASED VINTAGE WEIGHTS

Year [1]	Building and fixed equipment		Movable equipment		Interest	
	2014-based 23 years	FY 2010-based 25 years	2014-based 10 years	FY 2010-based 6 years	2014-based 21 years	FY 2010-based 22 years
1	.056	.061	.085	.165	.032	.030
2	.055	.059	.087	.160	.033	.030
3	.054	.053	.091	.167	.034	.032
4	.052	.050	.097	.167	.036	.033
5	.049	.046	.099	.169	.037	.035
6	.046	.043	.102	.171	.039	.037
7	.044	.041	.108		.041	.039
8	.043	.039	.109		.043	.040
9	.040	.036	.110		.044	.041
10	.038	.034	.112		.045	.043
11	.038	.034			.048	.045
12	.039	.034			.052	.047
13	.039	.033			.056	.048
14	.039	.032			.058	.048
15	.039	.031			.060	.050
16	.039	.031			.059	.052
17	.040	.032			.057	.055
18	.041	.034			.057	.058
19	.043	.035			.056	.060
20	.042	.036			.056	.060
21	.042	.038			.057	.058
22	.042	.039				.058
23	.042	.042				
24		.043				
25		.044				
26						
Total	1.000	1.000	1.000	1.000	1.000	1.000

Note: The vintage weights are calculated using thirteen decimals. For presentational purposes, we are displaying three decimals and therefore, the detail vintage weights may not add to 1.000 due to rounding.

[1] Year 1 represents the vintage weight applied to the farthest year while the vintage weight for year 23, for example, would apply to the most recent year.

Table 15 shows all the price proxies for the final 2014 based SNF market basket.

TABLE 15—PRICE PROXIES FOR THE FINAL 2014-BASED SNF MARKET BASKET

Cost category	Weight	Proposed price proxy
Total	100.0	
Compensation	60.4	
Wages and Salaries [1]	50.0	ECI for Wages and Salaries for Private Industry Workers in Nursing Care Facilities.
Employee Benefits [1]	10.5	ECI for Total Benefits for Private Industry Workers in Nursing Care Facilities.
Utilities	2.6	
Electricity	1.2	PPI Commodity for Commercial Electric Power.
Fuel: Oil and Gas	1.3	Blend of Fuel PPIs.
Water and Sewerage	0.2	CPI for Water and Sewerage Maintenance (All Urban Consumers).
Professional Liability Insurance	1.1	CMS Professional Liability Insurance Premium Index.
All Other	27.9	
Other Products	14.3	
Pharmaceuticals	7.3	PPI Commodity for Pharmaceuticals for Human Use, Prescription.
Food: Direct Purchase	3.1	PPI Commodity for Processed Foods and Feeds.
Food: Contract Purchase	0.7	CPI for Food Away From Home (All Urban Consumers).

TABLE 15—PRICE PROXIES FOR THE FINAL 2014-BASED SNF MARKET BASKET—Continued

Cost category	Weight	Proposed price proxy
Chemicals	0.2	Blend of Chemical PPIs.
Medical Instruments and Supplies	0.6	Blend of Medical Instruments and Supplies PPIs.
Rubber and Plastics	0.8	PPI Commodity for Rubber and Plastic Products.
Paper and Printing Products	0.8	PPI Commodity for Converted Paper and Paperboard Products.
Apparel	0.3	PPI Commodity for Apparel.
Machinery and Equipment	0.3	PPI Commodity for Machinery and Equipment.
Miscellaneous Products	0.3	PPI Commodity for Finished Goods Less Food and Energy.
All Other Services	13.6	
Labor-Related Services	7.4	
Professional Fees: Labor-related	3.8	ECI for Total Compensation for Private Industry Workers in Professional and Related.
Installation, Maintenance, and Repair Services	0.6	ECI for Total Compensation for All Civilian workers in Installation, Maintenance, and Repair.
Administrative and Facilities Support	0.5	ECI for Total Compensation for Private Industry Workers in Office and Administrative Support.
All Other: Labor-Related Services	2.5	ECI for Total Compensation for Private Industry Workers in Service Occupations.
Non Labor-Related Services	6.2	
Professional Fees: Nonlabor-Related	1.8	ECI for Total Compensation for Private Industry Workers in Professional and Related.
Financial Services	2.0	ECI for Total Compensation for Private Industry Workers in Financial Activities.
Telephone Services	0.5	CPI for Telephone Services.
Postage	0.2	CPI for Postage.
All Other: Nonlabor-Related Services	1.8	CPI for All Items Less Food and Energy.
Capital-Related Expenses	7.9	
Total Depreciation	2.9	
Building and Fixed Equipment	2.5	BEA's Chained Price Index for Private Fixed Investment in Structures, Nonresidential, Hospitals and Special Care—vintage weighted 23 years.
Movable Equipment	0.4	PPI Commodity for Machinery and Equipment—vintage weighted 10 years.
Total Interest	3.0	
For-Profit SNFs	0.8	Moody's—Average yield on AAA bonds, vintage weighted 21 years.
Government and Nonprofit SNFs	2.1	Moody's—Average yield on Domestic Municipal Bonds—vintage weighted 21 years.
Other Capital-Related Expenses	2.0	CPI for Owners' Equivalent Rent of Primary Residence.

Note: The cost weights are calculated using three decimal places. For presentational purposes, we are displaying one decimal and, therefore, the detailed cost weights may not add to the aggregate cost weights or to 100.0 due to rounding.

[1] Contract labor is distributed to wages and salaries and employee benefits based on the share of total compensation that each category represents.

c. Labor-Related Share

We define the labor-related share (LRS) as those expenses that are labor-intensive and vary with, or are influenced by, the local labor market. Each year, we calculate a revised labor-related share based on the relative importance of labor-related cost categories in the input price index. Effective beginning with FY 2018, we proposed to revise and update the labor-related share to reflect the relative importance of the 2014-based SNF market basket cost categories that we believe are labor-intensive and vary with, or are influenced by, the local labor market. For the proposed 2014-based SNF market basket, these are: (1) Wages and Salaries (including allocated contract labor costs as described above); (2) Employee Benefits (including allocated contract labor costs as described above); (3) Professional fees: Labor-related; (4) Administrative and Facilities Support Services; (5) Installation, Maintenance, and Repair services; (6) All Other: Labor-Related Services; and (7) a proportion of capital-related expenses. We proposed to continue to include a proportion of capital-related expenses because a portion of these expenses are deemed to be labor-intensive and vary with, or are influenced by, the local labor market. For example, a proportion of construction costs for a medical building would be attributable to local construction workers' compensation expenses.

Consistent with previous SNF market basket revisions and rebasings, the All Other: Labor-related services cost category is mostly comprised of building maintenance and security services (including, but not limited to, landscaping services, janitorial services, waste management services, and investigation and security services). Because these services tend to be labor-intensive and are mostly performed at the SNF facility (and therefore, unlikely to be purchased in the national market), we believe that they meet our definition of labor-related services.

The proposed inclusion of the Installation, Maintenance, and Repair Services cost category into the labor-related share remains consistent with the current labor-related share, since this cost category was previously included in the FY 2010-based SNF market basket All Other: Labor-related Services cost category. We proposed to establish a separate Installation, Maintenance, and Repair Services cost category so that we can use the ECI for Total Compensation for All Civilian Workers in Installation, Maintenance, and Repair to reflect the specific price

changes associated with these services. We also use this cost category in the 2012-based IRF market basket (80 FR 47059), 2012-based IPF market basket (80 FR 46667), and 2013-based LTCH market basket (81 FR 57091).

As discussed in the FY 2014 SNF PPS proposed rule (78 FR 26462), in an effort to determine more accurately the share of nonmedical professional fees (included in the 2014-based SNF market basket Professional Fees cost categories) that should be included in the labor-related share, we surveyed SNFs regarding the proportion of those fees that are attributable to local firms and the proportion that are purchased from national firms. Based on these weighted results, we determined that SNFs purchase, on average, the following portions of contracted professional services inside their local labor market:

- 78 percent of legal services.
- 86 percent of accounting and auditing services.
- 89 percent of architectural, engineering services.
- 87 percent of management consulting services.

Together, these four categories represent 3.3 percentage points of the total costs for the 2014-based SNF market basket. We applied the percentages from this special survey to their respective SNF market basket weights to separate them into labor-related and nonlabor-related costs. As a result, we proposed to designate 2.8 percentage points of the 3.3 percentage points to the labor-related share, with the remaining 0.5 percentage point is categorized as nonlabor-related.

For the proposed 2014-based SNF market basket, we conducted a similar analysis of home office data. The Medicare cost report CMS Form 2540–10 requires a SNF to report information regarding their home office provider. Approximately 57 percent of SNFs reported some type of home office information on their Medicare cost report for 2014 (for example, city, state, zip code). Using the data reported on the Medicare cost report, we compared the location of the SNF with the location of the SNF's home office. For the FY 2010-based SNF market basket, we used the Medicare HOMER database to determine the location of the provider's home office as this information was not available on the Medicare cost report CMS Form 2540–96. For the 2014-based SNF market basket, we proposed to determine the proportion of home office contract labor costs that should be allocated to the labor-related share based on the percent of total SNF home office contract labor costs as reported in Worksheet S–3, Part II attributable to those SNFs that had home offices located in their respective local labor markets—defined as being in the same Metropolitan Statistical Area (MSA). We determined a SNF's and home office's MSAs using their zip code information from the Medicare cost reports.

Using this methodology, we determined that 28 percent of SNFs' home office contract labor costs were for home offices located in their respective local labor markets. Therefore, we proposed to allocate 28 percent of home office expenses to the labor-related share. The FY 2010-based SNF market basket allocated 32 percent of home office expenses to the labor-related share.

In the proposed 2014-based SNF market basket, home office expenses that were subject to allocation based on the home office allocation methodology represent 0.7 percent of the 2014-based SNF market basket. Based on the home office results, we proposed to apportion 0.2 percentage point of the 0.7 percentage point figure into the labor-related share ($0.7 \times 0.28 = 0.193$, or 0.2) and designate the remaining 0.5 percentage point as nonlabor-related. Therefore, based on the two allocations mentioned above, we proposed to apportion 3.0 percentage points into the labor-related share. This amount is added to the portion of professional fees that we continue to identify as labor-related using the I–O data such as contracted advertising and marketing costs (0.8 percentage point of total operating costs) resulting in a Professional Fees: Labor-Related cost weight of 3.8 percent.

We did not receive any public comments on our proposed methodology for deriving the labor-related share. For the reasons discussed above and in the FY 2018 SNF PPS proposed rule, we are finalizing our proposals, without modification, as discussed above to update and revise the labor-related share effective October 1, 2017, to reflect the relative importance of the following 2014-based SNF market basket cost weights that we believe are labor-intensive and vary with, or are influenced by, the local labor market: (1) Wages and Salaries (including allocated contract labor costs as described above); (2) Employee Benefits (including allocated contract labor costs as described above); (3) Professional fees: Labor-related; (4) Administrative and Facilities Support Services; (5) Installation, Maintenance, and Repair services; (6) All Other: Labor-Related Services; and (7) a proportion of capital-related expenses.

Table 16 compares the 2014-based labor-related share and the FY 2010-based labor-related share based on the relative importance of IGI's most recent second quarter 2017 forecast with historical data through the first quarter of 2017. The FY 2018 SNF PPS proposed rule (82 FR 21040) reflected IGI's first quarter 2017 forecast with historical data through the fourth quarter of 2016. As stated in the FY 2018 SNF PPS proposed rule (82 FR 21019), our policy has been that, if more recent data becomes available (for example, a more recent estimate of the SNF market basket and/or MFP adjustment), we would use such data, if appropriate, to determine the SNF market basket percentage change, labor-related share relative importance, forecast error adjustment, and MFP adjustment in the SNF PPS final rule.

We note that in Table 16 of the FY 2018 SNF PPS proposed rule (82 FR 21041), we misreported the FY 2017 labor-related share as 69.1 percent (this was the FY 2016 labor-related share (80 FR 46402)). The FY 2017 labor-related share was 68.8 percent as finalized in the FY 2017 SNF PPS final rule (81 FR 51979, 51980). We present the FY 2017 labor-related share in Table 16 below.

TABLE 16—FY 2018 AND FY 2017 SNF LABOR-RELATED SHARE

	Relative importance, labor-related, FY 2018 (2014-based index) 2017:Q2 forecast	Relative importance, labor-related, FY 2017 (FY 2010-based index) 2016:Q2 forecast
Wages and Salaries [1]	50.3	48.8
Employee Benefits [1]	10.2	11.1

TABLE 16—FY 2018 AND FY 2017 SNF LABOR-RELATED SHARE—Continued

	Relative importance, labor-related, FY 2018 (2014-based index) 2017:Q2 forecast	Relative importance, labor-related, FY 2017 (FY 2010-based index) 2016:Q2 forecast
Professional fees: Labor-Related	3.7	3.4
Administrative and Facilities Support Services	0.5	0.5
Installation, Maintenance and Repair Services [2]	0.6	n/a
All Other: Labor-related Services	2.5	2.3
Capital-related (.391)	3.0	2.7
Total	70.8	68.8

[1] The Wages and Salaries and Employee Benefits cost weight reflect contract labor costs as described above.
[2] Previously classified in the All Other: Labor-related services cost category in the FY 2010-based SNF market basket.
Source: IHS Global Inc. 2nd quarter 2017 forecast with historical data through 1st quarter 2017.

The FY 2018 SNF labor-related share (LRS) is 2.0 percentage points higher than the FY 2017 SNF LRS, which is based on the FY 2010-based SNF market basket relative importance. This implies an increase in the quantity of the labor-related services because rebasing the index contributed significantly to the increase. Also contributing to the higher labor-related share is a higher capital-related cost weight in the 2014-based SNF market basket compared to the FY 2010-based SNF market basket. As stated above, we include a proportion of capital-related expenses in the labor-related share as we believe a portion of these expenses (such as construction labor costs) are deemed to be labor-intensive and vary with, or are influenced by, the local labor market.

d. Market Basket Estimate for the FY 2018 SNF PPS Update

As discussed previously in this final rule, beginning with the FY 2018 SNF PPS update, we are adopting the 2014-based SNF market basket as the appropriate market basket of goods and services for the SNF PPS. Based on IHS Global Inc.'s (IGI) second quarter 2017 forecast with historical data through the first quarter of 2017, the most recent estimate of the 2014-based SNF market basket for FY 2018 is 2.6 percent. As stated above, the FY 2018 SNF PPS proposed rule reflected IGI's first quarter 2017 forecast with historical data through the fourth quarter of 2016. IGI is a nationally recognized economic and financial forecasting firm that contracts with CMS to forecast the components of CMS' market baskets.

Table 17 compares the 2014-based SNF market basket and the FY 2010-based SNF market basket percent changes. For the historical period between FY 2013 and FY 2016, the average difference between the two market baskets is −0.3 percentage point. This is primarily the result of the lower pharmaceuticals cost category weight, increased Fuel: Oil and Gas cost category weight, and the change in the Fuels price proxy. For the forecasted period between FY 2017 and FY 2019, there is no difference in the average growth rate.

TABLE 17—2014-BASED SNF MARKET BASKET AND FY 2010-BASED SNF MARKET BASKET, PERCENT CHANGES: 2013 TO 2019

Fiscal year (FY)	2014-based SNF market basket	FY 2010-based SNF market basket
Historical data:		
FY 2013	1.6	1.8
FY 2014	1.6	1.7
FY 2015	1.8	2.3
FY 2016	1.9	2.3
Average FY 2013–2016	1.7	2.0
Forecast:		
FY 2017	2.7	2.7
FY 2018	2.6	2.7
FY 2019	2.7	2.7
Average FY 2017–2019	2.7	2.7

Source: IHS Global Inc. 2nd quarter 2017 forecast with historical data through 1st quarter 2017.

While we ordinarily would adopt the use of this 2014-based SNF market basket percentage to update the SNF PPS per diem rates for FY 2018, we note that section 411(a) of the MACRA amended section 1888(e) of the Act to add section 1888(e)(5)(B)(iii) of the Act, which establishes a special rule for FY 2018 that requires the market basket percentage, after the application of the productivity adjustment, to be 1.0 percent. In accordance with section 1888(e)(5)(B)(iii) of the Act, we will use a market basket percentage of 1.0 percent to update the federal rates set forth in this final rule. We proposed to use the 2014-based SNF market basket to determine the market basket percentage update for the SNF PPS per diem rates effective FY 2019. For the reasons discussed above and in the FY 2018 SNF PPS proposed rule, we are finalizing our proposal to use the 2014-based SNF market basket to determine

the market basket percentage update for the SNF PPS per diem rates, effective FY 2019. In addition, as stated in section III.D.1.d. in this preamble, we are adopting the use of the 2014-based SNF market basket to determine the labor-related share effective October 1, 2017.

2. Skilled Nursing Facility (SNF) Quality Reporting Program (QRP)

a. Background and Statutory Authority

Section 1888(e)(6)(A)(i) of the Act, as added by section 2(c)(4) of the Improving Medicare Post-Acute Care Transformation Act of 2014 (IMPACT Act), requires that for fiscal years beginning with FY 2018, in the case of a SNF that does not submit data as applicable in accordance with sections 1888(e)(6)(B)(i)(II) and (III) of the Act for a fiscal year, the Secretary reduce the market basket percentage described in section 1888(e)(5)(B)(i) of the Act for payment rates during that fiscal year by two percentage points. In section III.B.2. of this final rule, we discuss revisions in the market basket update regulations at § 413.337(d) that will implement this provision. In accordance with this statutory mandate, we have implemented a SNF Quality Reporting Program (QRP), which we believe promotes higher quality and more efficient health care for Medicare beneficiaries. 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 a full discussion of the statutory background and policy considerations that have shaped the SNF QRP.

When we use the term ''FY (year)SNF QRP,'' we are referring to the fiscal year for which the SNF QRP requirements applicable to that fiscal year must be met in order for a SNF to receive the full market basket percentage when calculating the payment rates applicable to it for that fiscal year.

The IMPACT Act (Pub. L. 113–185) amended Title XVIII of the Act, in part, by adding a new section 1899B that requires the Secretary to establish new data reporting requirements for certain post-acute care (PAC) providers, including SNFs. Specifically, new sections 1899B(a)(1)(A)(ii) and (iii) of the Act require SNFs, inpatient rehabilitation facilities (IRFs), Long Term Care Hospitals (LTCHs), and home health agencies (HHAs), under the provider-type's respective quality reporting program (which, for SNFs, is found at section 1888(e)(6) of the Act), to report data on quality measures specified under section 1899B(c)(1) of the Act for at least five domains, and data on resource use and other measures specified under section 1899B(d)(1) of the Act for at least three domains. Section 1899B(a)(1)(A)(i) of the Act further requires each of these PAC provider-types to report under its respective quality reporting program standardized resident assessment data in accordance with subsection (b), for at least the quality measures specified under subsection (c)(1), and that is for at least five specific categories: Functional status; cognitive function and mental status; special services, treatments, and interventions; medical conditions and co-morbidities; and impairments. Section 1899B(a)(1)(B) of the Act requires that all of the data that must be reported in accordance with section 1899B(a)(1)(A) of the Act be standardized and interoperable to allow for the exchange of the information among PAC providers and other providers and the use of such data to enable access to longitudinal information and to facilitate coordinated care. We refer readers to the FY 2016 SNF PPS final rule (80 FR 46427 through 46429) for additional information on the IMPACT Act and its applicability to SNFs.

b. General Considerations Used for Selection of Quality 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,[3] which incorporates the three broad aims of the National Quality Strategy.[4]

As part of our consideration for measures for use in the SNF QRP, we review and evaluate measures that have been implemented in other programs and take into account measures that have been endorsed by NQF for provider settings other than the SNF setting. We have previously adopted measures that we referred to as ''applications'' of those measures. We have received questions pertaining to the term ''application'' and want to clarify that when we refer to a proposed or implemented measure as an ''application of'' the measure, we mean that the measure will be used in the SNF setting, rather than the setting for which it was endorsed by the NQF. For example, in the FY 2016 SNF PPS final rule (80 FR 46440 through 46444), we adopted a measure entitled Application of Percent of Residents Experiencing One or More Falls With Major Injury (Long Stay) (NQF #0674), which is currently endorsed for the nursing home setting but not for the SNF setting. For such measures, we intend to seek NQF endorsement for the SNF setting, and if the NQF endorses one or more of them, we will update the title of the measure to remove the reference to ''application''.

We received several comments generally related to the proposed measures, the IMPACT Act, NQF endorsement, and training needs. The comments and our responses are discussed below.

Comment: A few commenters expressed concern that CMS has not provided a timeline for seeking NQF endorsement for non-NQF-endorsed quality measures in the SNF QRP. One commenter expressed further concern that non-NQF-endorsed measures may be implemented before undergoing adequate testing, as required for NQF endorsement. Another commenter expressed concern regarding the adequacy of resources allocated to complete necessary testing and obtain consensus endorsement for measures as required by the IMPACT Act. All commenters commenting on this topic requested further information from CMS regarding the process and timeline for seeking NQF endorsement.

Response: We recognize that the NQF endorsement process is an important part of measure development and plan to submit non-NQF-endorsed quality measures in the SNF QRP adopted in this rule for NQF endorsement as soon as feasible, with an intended timeframe of 2018. With regard to adequate testing prior to implementation, we wish to note that we engage in multiple testing activities prior to measure implementation. These activities include testing of items and measures in their intended settings, public posting of measure testing data, when possible, seeking public comment on measures in the various stages of their development, and utilization of technical expert input on measure development, including expert evaluation of the validity and importance of measures. We interpret the commenter's comment regarding the adequacy of the resources necessary to obtain consensus endorsement as efforts to engage stakeholders. We believe that we commit an adequate level of resources to the measure development process and the NQF endorsement process. Such resources are outlined above and include engaging in pilot

[3] *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/CMS-Quality-Strategy.html.*

[4] *http://www.ahrq.gov/workingforquality/nqs/nqs2011annlrpt.htm.*

testing with providers, seeking public comment, convening TEPs, and engaging subject matter experts to provide feedback throughout the measure development process.

Comment: One commenter recommended aligning the SNF QRP quality measures with other CMS initiatives such as the Financial Alignment Initiative, the value-based payment program and the Medicaid managed care initiatives under the Section 1115 waiver authorities.

Response: We acknowledge the value of aligning the SNF QRP measures to other CMS initiatives and we will seek to align measures with other initiatives in an effort to reduce provider burden where feasible.

(1) Measuring and Accounting for Social Risk Factors in the SNF QRP

In, the FY 2018 SNF PPS proposed rule (82 FR 21042 through 21043), we discussed accounting for social risk factors in the SNF QRP. We stated that we consider related factors that may affect measures in the SNF QRP. We understand that social risk factors such as income, education, race and ethnicity, employment, disability, community resources, and social support (certain factors of which are also sometimes referred to as socioeconomic status (SES) factors or socio-demographic status (SDS) factors) play a major role in health. One of our core objectives is to improve beneficiary outcomes including reducing health disparities, and we want to ensure that all beneficiaries, including those with social risk factors, receive high quality care. In addition, we seek to ensure that the quality of care furnished by providers and suppliers is assessed as fairly as possible under our programs while ensuring that beneficiaries have adequate access to excellent care.

We have been reviewing reports prepared by the Office of the Assistant Secretary for Planning and Evaluation (ASPE) and the National Academies of Sciences, Engineering, and Medicine on the issue of measuring and accounting for social risk factors in CMS' quality measurement and payment programs, and considering options on how to address the issue in these programs. On December 21, 2016, ASPE submitted a Report to Congress on a study it was required to conduct under section 2(d) of the IMPACT Act. The study analyzed the effects of certain social risk factors of Medicare beneficiaries on quality measures and measures of resource use used in one or more of nine Medicare value-based purchasing programs.[5] The report also included considerations for strategies to account for social risk factors in these programs. In a January 10, 2017 report released by The National Academies of Sciences, Engineering, and Medicine, that body provided various potential methods for measuring and accounting for social risk factors, including stratified public reporting.[6]

In addition, the NQF undertook a 2-year trial period in which new measures, measures undergoing maintenance review, and measures endorsed with the condition that they enter the trial period were assessed to determine whether risk adjustment for selected social risk factors was appropriate for these measures. This trial entailed temporarily allowing inclusion of social risk factors in the risk-adjustment approach for these measures. The trial has concluded and NQF will issue recommendations on the future inclusion of social risk factors in risk adjustment for quality measures.

As we continue to consider the analyses and recommendations from these reports and await the recommendations of the NQF trial on risk adjustment for quality measures, we are continuing to work with stakeholders in this process. As we have previously communicated, we are concerned about holding providers to different standards for the outcomes of their patients with social risk factors because we do not want to mask potential disparities or minimize incentives to improve the outcomes for disadvantaged populations. Keeping this concern in mind, while we sought input on this topic previously, we continue to seek public comment on whether we should account for social risk factors in measures in the SNF QRP, and if so, what method or combination of methods would be most appropriate for accounting for social risk factors. Examples of methods include: Confidential reporting to providers of measure rates stratified by social risk factors, public reporting of stratified measure rates, and potential risk adjustment of a particular measure as appropriate based on data and evidence.

In addition, in the FY 2018 SNF PPS proposed rule (82 FR 21042 through 21043), we sought public comment on which social risk factors might be most appropriate for reporting stratified measure scores and/or potential risk adjustment of a particular measure. Examples of social risk factors include, but are not limited to, dual eligibility/low-income subsidy, race and ethnicity, and geographic area of residence. We also sought comments on which of these factors, including current data sources where this information would be available, could be used alone or in combination, and whether other data should be collected to better capture the effects of social risk. We will take commenters' input into consideration as we continue to assess the appropriateness and feasibility of accounting for social risk factors in the SNF QRP. We note that any such changes would be proposed through future notice and comment rulemaking.

We look forward to working with stakeholders as we consider the issue of accounting for social risk factors and reducing health disparities in CMS programs. Of note, implementing any of the above methods would be taken into consideration in the context of how this and other CMS programs operate (for example, data submission methods, availability of data, statistical considerations relating to reliability of data calculations, among others), so we sought comment on operational considerations. We are committed to ensuring that Medicare beneficiaries have access to and receive excellent care, and that the quality of care furnished by providers and suppliers is assessed fairly in CMS programs. A discussion of the comments we received on this topic, along with our responses, appears below.

Comment: Some commenters were generally supportive of accounting for social risk factors for the SNF QRP quality measures. Many commenters stated that there was evidence demonstrating that these factors can have substantial influence on patient health outcomes. Some commenters noted that social risk factors are beyond the control of the facility and were concerned that without risk adjustment, differences in quality scores may reflect differences in patient populations rather than differences in quality. Commenters also recommended incorporating the results of the NQF SES trial period into consideration of adopting risk-adjustment strategies.

A few commenters, while acknowledging the influence of social risk factors on health outcomes, cautioned against adjusting for them in quality measurement due to the potential for unintended consequences. These commenters expressed concern

[5] Office of the Assistant Secretary for Planning and Evaluation. 2016. Report to Congress: Social Risk Factors and Performance Under Medicare's Value-Based Purchasing Programs. Available at *https://aspe.hhs.gov/pdf-report/report-congress-social-risk-factors-and-performance-under-medicares-value-based-purchasing-programs.*

[6] National Academies of Sciences, Engineering, and Medicine. 2017. Accounting for social risk factors in Medicare payment. Washington, DC: The National Academies Press.

over the possibility that risk-adjusted measures may remove incentives for quality improvement among facilities that serve higher levels of underserved populations.

Regarding the methodology for risk adjustment, some commenters made specific recommendations regarding the type of risk adjustment that should be used. One commenter suggested that both risk stratification and statistical risk adjustment be used. Commenters stated that any risk stratification should be considered on a measure-by-measure basis, and that measures that are broadly within the control of the facility and reflective of direct care, such as pressure ulcers, should not be stratified. Multiple commenters recommended that we conduct further research and testing of risk-adjustment methods. A few commenters noted the importance of continued monitoring of the effect of social risk factors on health outcomes and on the SNF QRP over time. Other commenters recommended adjusting for social risk factors, specifically for resource use measures assessing potentially preventable readmissions, Medicare Spending Per Beneficiary, and social and environmental risk factors for functional improvement measures. Another commenter noted there are meaningful SES, clinical or other differences between traditional Medicare versus Medicare Advantage (MA) enrollees that could affect comparisons between facilities with different proportion of Medicare Advantage and Part A stays. The commenter further requested that this possibility should be investigated.

In addition to support for our suggested categories of race and ethnicity, dual eligibility status, and geographical location, specific social risk factors suggested by commenters included: Patient-level factors such as lack of personal resources, education level, healthcare literacy, employment, and limited English proficiency. Commenters also suggested community resources and other factors such as access to adequate food, medications, availability of primary care and therapy services, living conditions including living alone, lack of an adequate support system or caregiver availability. Regarding sources for data collection, a commenter suggested the use of confidential patient-reported data to determine social risk and another commenter suggested using confidential electronic health records to collect data relevant to social risk factors.

There were a few comments discussing confidential and public reporting of data adjusted for social risk factors. While a commenter recommended that risk-stratified measures should be publicly reported for purposes of transparency, another commenter noted that the public reporting of stratified rates could create a disincentive to care for disadvantaged populations.

Response: As we have previously stated, we are concerned about holding providers to different standards for the outcomes of their patients with social risk factors, because we do not want to mask potential disparities. We believe that the path forward should incentivize improvements in health outcomes for disadvantaged populations while ensuring that beneficiaries have adequate access to excellent care.

We will consider all suggestions as we continue to assess each measure and the overall program. We intend to explore options including but not limited to measure stratification by social risk factors in a consistent manner across programs, informed by considerations of stratification methods described in section IX.A.13 of the preamble of the FY 2018 IPPS/LTCH PPS final rule. We thank commenters for this important feedback and will continue to consider options to account for social risk factors that would allow us to view disparities and potentially incentivize improvement in care for patients and beneficiaries. We will also consider providing feedback to providers on outcomes for individuals with social risk factors in confidential reports.

c. Collection of Standardized Resident Assessment Data Under the SNF QRP

(1) Definition of Standardized Resident Assessment Data

Section 1888(e)(6)(B)(i)(III) of the Act requires that for fiscal year 2019 (beginning October 1, 2018) and each subsequent year, SNFs report standardized resident assessment data required under section 1899B(b)(1) of the Act. For purposes of meeting this requirement, section 1888(e)(6)(B)(ii) of the Act requires a SNF to submit the standardized resident assessment data required under section 1819(b)(3) of the Act using the standard instrument designated by the state under section 1819(e)(5) of the Act.

For purposes of the SNF QRP, we refer to beneficiaries who receive services from SNFs as ''residents,'' and we collect certain information about the SNF services they receive using the Resident Assessment Instrument Minimum Data Set (MDS).

Section 1899B(b)(1)(B) of the Act describes standardized resident assessment data as data required for at least the quality measures described in sections 1899B(c)(1) of the Act and that is for the following categories:

- Functional status, such as mobility and self-care at admission to a PAC provider and before discharge from a PAC provider;
- Cognitive function, such as ability to express ideas and to understand and mental status, such as depression and dementia;
- Special services, treatments and interventions such as the need for ventilator use, dialysis, chemotherapy, central line placement and total parenteral nutrition;
- Medical conditions and comorbidities such as diabetes, congestive heart failure and pressure ulcers;
- Impairments, such as incontinence and an impaired ability to hear, see or swallow; and
- Other categories deemed necessary and appropriate.

As required under section 1899B(b)(1)(A) of the Act, the standardized resident assessment data must be reported at least for SNF admissions and discharges, but the Secretary may require the data to be reported more frequently.

In the FY 2018 SNF PPS proposed rule (82 FR 21043 through 21044), we proposed to define the standardized resident assessment data that SNFs must report to comply with section 1888(e)(6) of the Act, as well as the requirements for the reporting of these data. The collection of standardized resident assessment data is critical to our efforts to drive improvement in health care quality across the four post-acute care (PAC) settings to which the IMPACT Act applies. We intend to use these data for a number of purposes, including facilitating their exchange and longitudinal use among health care providers to enable high quality care and outcomes through care coordination, as well as for quality measure calculation, and identifying comorbidities that might increase the medical complexity of a particular admission.

SNFs are currently required to report resident assessment data through the MDS by responding to an identical set of assessment questions using an identical set of response options (we refer to each solitary question/response option as a data element and we refer to a group of questions/responses as data elements), both of which incorporate an identical set of definitions and standards. The primary purpose of the identical questions and response options is to ensure that we collect a set of standardized resident assessment data elements across SNFs which we

can then use for a number of purposes, including SNF payment and measure calculation for the SNF QRP.

LTCHs, IRFs, and HHAs are also required to report patient assessment data through their applicable PAC assessment instruments, and they do so by responding to identical assessment questions developed for their respective settings using an identical set of response options (which incorporate an identical set of definitions and standards). Like the MDS, the questions and response options for each of these other PAC assessment instruments are standardized across the PAC provider type to which the PAC assessment instrument applies. However, the assessment questions and response options in the four PAC assessment instruments are not currently standardized with each other. As a result, questions and response options that appear on the MDS cannot be readily compared with questions and response options that appear, for example, on the Inpatient Rehabilitation Facility-Patient Assessment Instrument (IRF–PAI) the PAC assessment instrument used by IRFs. This is true even when the questions and response options are similar. This lack of standardization across the four PAC provider types has limited our ability to compare one PAC provider type with another for purposes such as care coordination and quality improvement.

To achieve a level of standardization across SNFs, LTCHs, IRFs, and HHAs that enables us to make comparisons between them, we proposed to define ''standardized resident assessment data'' [7] as patient or resident assessment questions and response options that are identical in all four PAC assessment instruments, and to which identical standards and definitions apply. Standardizing the questions and response options across the four PAC assessment instruments will also enable the data to be interoperable allowing it to be shared electronically, or otherwise, between PAC provider types. It will enable the data to be comparable for various purposes, including the development of cross-setting quality measures, which may enhance provider and resident choice when selecting a post-acute care setting that will deliver the best outcome possible, and to inform payment models that take into account patient characteristics rather than setting, as described in the IMPACT Act.

We sought comment on this definition. A discussion of these comments, along with our responses, appears below.

Comment: Most commenters expressed general support for the definition of standardized patient/resident assessment data. One commenter further expressed support for CMS efforts to standardize assessment data to promote care coordination and quality improvements as required under the IMPACT Act.

Response: We thank the commenters for their support.

Final Decision: We are finalizing our definition of standardized resident assessment data as proposed.

(2) General Considerations Used for the Selection of Standardized Resident Assessment Data

As part of our effort to identify appropriate standardized resident assessment data for purposes of collecting under the SNF QRP, we sought input from the general public, stakeholder community, and subject matter experts on items that would enable person-centered, high quality health care, as well as access to longitudinal information to facilitate coordinated care and improved beneficiary outcomes.

To identify optimal data elements for standardization, our data element contractor organized teams of researchers for each category, and each team worked with a group of advisors made up of clinicians and academic researchers with expertise in PAC. Information-gathering activities were used to identify data elements, as well as key themes related to the categories described in section 1899B(b)(1)(B) of the Act. In January and February 2016, our data element contractor also conducted provider focus groups for each of the four PAC provider types, and a focus group for consumers that included current or former PAC patients and residents, caregivers, ombudsmen, and patient advocacy group representatives. The Development and Maintenance of Post-Acute Care Cross-Setting Standardized Patient Assessment Data Focus Group Summary Report is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

We also assembled a 16-member TEP that met on April 7 and 8, 2016, and January 5 and 6, 2017, in Baltimore, Maryland, to provide expert input on data elements that are currently in each PAC assessment instrument, as well as data elements that could be standardized. The Development and Maintenance of Post-Acute Care Cross-Setting Standardized Patient Assessment Data TEP Summary Reports are available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

As part of the environmental scan, data elements currently in the four existing PAC assessment instruments were examined to see if any could be considered for proposal as standardized resident assessment data. Specifically, this evaluation included consideration of data elements in OASIS–C2 (effective January 2017); IRF–PAI, v1.4 (effective October 2016); LCDS, v3.00 (effective April 2016); and MDS 3.0, v1.14 (effective October 2016). Data elements in the standardized assessment instrument that we tested in the Post-Acute Care Payment Reform Demonstration (PAC PRD)—the Continuity Assessment Record and Evaluation (CARE) were also considered. A literature search was also conducted to determine whether additional data elements to propose as standardized resident assessment data could be identified.

We additionally held four Special Open Door Forums (SODFs) on October 27, 2015; May 12, 2016; September 15, 2016; and December 8, 2016, to present data elements we were considering and to solicit input. At each SODF, some stakeholders provided immediate input, and all were invited to submit additional comments via the CMS IMPACT Mailbox at *PACQualityInitiative@cms.hhs.gov.*

We also convened a meeting with federal agency subject matter experts (SMEs) on May 13, 2016. In addition, a public comment period was open from August 12, to September 12, 2016, to solicit comments on detailed candidate data element descriptions, data collection methods, and coding methods. The IMPACT Act Public Comment Summary Report containing the public comments (summarized and verbatim) and our responses, is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

We specifically sought to identify standardized resident assessment data that we could feasibly incorporate into the LTCH, IRF, SNF, and HHA assessment instruments and that have

[7] The FY 2018 SNF PPS proposed rule (82 FR 21044) used the term ''standardized patient assessment data.'' For purposes of the final rule we use the term ''standardized resident assessment data''.

the following attributes: (1) Being supported by current science; (2) testing well in terms of their reliability and validity, consistent with findings from the Post-Acute Care Payment Reform Demonstration (PAC PRD); (3) the potential to be shared (for example, through interoperable means) among PAC and other provider types to facilitate efficient care coordination and improved beneficiary outcomes; (4) the potential to inform the development of quality, resource use and other measures, as well as future payment methodologies that could more directly take into account individual beneficiary health characteristics; and (5) the ability to be used by practitioners to inform their clinical decision and care planning activities. We also applied the same considerations that we apply with quality measures, including the CMS Quality Strategy which is framed using the three broad aims of the National Quality Strategy.

d. Policy for Retaining SNF QRP Measures and Application of That Policy to Standardized Resident Assessment Data

In the FY 2016 SNF PPS final rule (80 FR 46431 through 46432), we adopted our policy for measure removal and also finalized that when we initially adopt a measure for the SNF QRP, 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. In the FY 2018 SNF PPS proposed rule (82 FR 21044) we proposed to apply this policy to the standardized resident assessment data that we adopt for the SNF QRP.

We sought public comment on our proposal. A discussion of these comments, along with our responses, appears below.

Comment: Several commenters supported applying the existing policy for retaining SNF QRP measures to standardized resident assessment data.

Response: We thank the commenters for their support.

Final Decision: After consideration of the public comments we received, we are finalizing our proposal to apply the policy for retaining SNF QRP measures to the standardized resident assessment data as proposed.

e. Policy for Adopting Changes to SNF QRP Measures and Application of That Policy to Standardized Resident Assessment Data

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 in the FY 2018 SNF PPS proposed rule (82 FR 21044 through 20145). We did propose to apply this policy to the standardized resident assessment data that we adopt for the SNF QRP.

We sought public comment on our proposal. A discussion of these comments, along with our responses, appears below.

Comment: All commenters who commented on this topic expressed support for our subregulatory process for adopting non-substantive changes to SNF QRP measures, recognizing that the measures will require adjustments over time to reflect changes in practice or populations. All of these commenters also specifically expressed support for our proposal to apply this approach to the standardized resident assessment data proposed for the SNF QRP. Many of these commenters further supported our policy to make substantive changes to quality measures using the rulemaking process. The commenters also recognized that corrections and adjustments to measures may become necessary over time and that we will provide a clear rationale for such changes, as well as a mechanism for public comment on these changes.

Response: We appreciate the commenters' support.

Final Decision: After consideration of the public comments we received, we are finalizing our proposal to apply our policy for adopting changes to the SNF QRP measures to the standardized resident assessment data as proposed.

f. Quality Measures Currently Adopted for the SNF QRP

The SNF QRP currently has seven adopted measures as outlined in Table 18.

TABLE 18—QUALITY MEASURES CURRENTLY ADOPTED FOR THE SNF QRP

Short name	Measure name & data source
Resident Assessment Instrument Minimum Data Set	
Pressure Ulcers	Percent of Residents or Patients with Pressure Ulcers that are New or Worsened (Short Stay) (NQF #0678).
Application of Falls	Application of the NQF-endorsed Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay) (NQF #0674).*
Application of Functional Assessment/Care Plan	Application of Percent of LTCH Patients with an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function (NQF #2631).*
DRR	Drug Regimen Review Conducted with Follow-Up for Identified Issues-Post Acute Care (PAC) Skilled Nursing Facility Quality Reporting Program.*
Claims-based	
MSPB	Total Estimated Medicare Spending Per Beneficiary (MSPB)—Post Acute Care (PAC) Skilled Facility (SNF) Quality Reporting Program (QRP).*
DTC	Discharge to Community-Post Acute Care (PAC) Skilled Nursing Facility (SNF) Quality Reporting Program (QRP).*
PPR	Potentially Preventable 30-Day Post-Discharge Readmission Measure for Skilled Nursing Facility Quality Reporting Program.*

* Not currently NQF-endorsed for the SNF Setting.

We received several comments about quality measures currently adopted for the SNF QRP which are summarized and discussed below.

Comment: A few commenters expressed views regarding the Potentially Preventable 30-Day Post-Discharge Readmission Measure for SNF QRP, a measure previously finalized in the FY 2017 SNF PPS final rule (81 FR 52030 through 52034). Comments included recommendations for

additional testing and evaluation of the PPR definition and measure exclusions. One commenter supported the public reporting thresholds. Another commenter requested that patient-level data be made available to SNFs to facilitate quality improvement and review and corrections. We also received some comments related to accounting for social risk factors.

Response: While we received comments regarding this previously finalized measure, the changes we proposed pertain only to the years of data used to calculate this measure and therefore we consider these comments to be out of scope of this current rule. We did address these issues in the FY 2017 SNF PPS final rule (81 FR 52030 through 52034), and we refer the reader to that detailed discussion. We continue to believe that the measure specifications are appropriate for this measure. We also refer readers to section III.D.2.b.1 of this rule for responses to comments received related to social risk factors for this measure.

Comment: We received a comment regarding the Drug Regimen Review Conducted with Follow-Up for Identified Issues-PAC SNF QRP measure, a measure previously finalized in the FY 2017 SNF PPS final rule. The commenter expressed support for MedPAC comments regarding the measure, including the MedPAC recommendation that we develop a measure to evaluate PAC provider support for medication reconciliation throughout the care continuum, including provider transfer of the patient medication list to the follow-up provider at patient discharge. The commenter stated the importance of provider access to patient medication lists and suggested that requiring providers to transmit the patient medication list to the follow-up provider at discharge may improve patient safety and prevent avoidable readmissions.

Response: We appreciate the comments received for this finalized measure. We refer readers to the FY 2017 SNF PPS final rule (81 FR 52034 through 52039) for detailed responses related to the previously finalized Drug Regimen Review Conducted with Follow-Up for Identified Issues-PAC SNF QRP measure.

Comment: A few commenters expressed views regarding the Medicare Spending per Beneficiary-PAC SNF QRP, a measure finalized in the FY 2017 SNF PPS final rule (81 FR 52014 through 52021). Commenters addressed the risk-adjustment approach, clinically unrelated services, confidential feedback reporting, accounting for social risk factors, MSPB–PAC measure alignment, and unintended consequences related to implementation of the measure. One commenter felt that the measure was confusing, and that patients and providers might incorrectly interpret it as a measure of quality rather than efficiency. Another commenter encouraged CMS to utilize claims and patient assessment data to incorporate functional status into the risk-adjustment. Another commenter expressed concern that PAC providers' performance on this measure would focus on costs per patient, without fully accounting for patient outcomes, and that efficiency should not be based solely on the MSPB–PAC measures. This commenter also noted that this measure may result in limiting access to certain patients. One commenter stated that the MSPB–PAC measures should be more uniformly defined so as to facilitate a meaningful comparison of spending for beneficiaries across PAC settings. Another commenter felt that the measure was flawed with regard to putting SNFs at risk for post-discharge services beyond their control. The commenter encouraged CMS to provide additional details regarding the types of services that would be considered ''included and associated services.'' Another commenter urged CMS to provide the opportunity for confidential feedback between CMS and providers before publicly displaying the MSPB–PAC measures.

Response: While we received comments regarding the previously finalized measure, Medicare Spending per Beneficiary-PAC SNF QRP, since no changes were proposed to this measure, we consider comments received to be outside the scope of the current rule. We addressed these issues in the FY 2017 SNF PPS final rule (81 FR 52014 through 52021), and we refer readers to that detailed discussion. We continue to believe that the measure specifications, including the risk-adjustment, are appropriate for this measure. With regard to comments related to accounting for social risk factors, we refer readers to section III.D.2.b.1. of this rule.

Comment: We received comments related to the Discharge to Community-PAC SNF QRP measure, a measure previously finalized in the FY 2017 SNF PPS final rule. Comments included suggestions to adjust for sociodemographic and socioeconomic risk factors and caregiver support, to adjust for factors unique to providers offering dedicated services to specialty residents (for example, those with HIV/AIDS) who may encounter greater challenges with community transitions, to exclude patients who died in the observation window following return to a community setting, to distinguish between a patient's return to home in the community versus home in a custodial nursing facility, to assess reliability and validity of the claims discharge status code used to calculate the measure, and to submit the measure for NQF endorsement. Commenters also shared concerns about risk adjustment for social factors as this could mask disparities in care, potential unintended consequences for patients expected to have difficult transitions to the community such as decreased PAC access and increased healthcare costs due to more costly acute care stays, lack of adjustment for regional differences in community-based needs and supports, and lack of adjustment for patients' goals in the community, such as those seeking end-of-life care outside of formal hospice services.

Response: While we received comments regarding the previously finalized Discharge to Community-PAC SNF QRP measure, since no changes were proposed to this measure, we consider comments received to be outside the scope of the current rule. We previously responded to comments on these topics in the FY 2017 SNF PPS final rule (81 FR 52021 through 52029); we refer the commenters to the FY 2017 SNF PPS final rule for a detailed response on these issues. We also note that in the FY 2018 SNF PPS proposed rule (81 FR 21058), we sought comment on the exclusion of baseline nursing facility residents as a potential future modification of the Discharge to Community-PAC SNF QRP measure. We refer readers to section III.D.2.i.1 of this final rule for a discussion of this issue. We also refer readers to section III.D.2.b.1. of this final rule for responses to comments received related to accounting for social risk factors for the Discharge to Community-PAC SNF QRP measure.

g. SNF QRP Quality Measures Beginning With the FY 2020 SNF QRP

In the FY 2018 SNF PPS proposed rule (82 FR 21045 through 21057), beginning with the FY 2020 SNF QRP, in addition to the quality measures we are retaining under our policy described in section III.D.2.f. of this final rule, we proposed to remove the current pressure ulcer measure entitled Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short Stay) (NQF #0678) and to replace it with a modified version of the measure entitled Changes in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury and to adopt four function

outcome measures on resident functional status. We also proposed to characterize the data elements described below as standardized resident assessment data under section 1899B(b)(1)(B) of the Act that must be reported by SNFs under the SNF QRP through the MDS.

The measures are as follows:

- Changes in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury.
- Application of IRF Functional Outcome Measure: Change in Self-Care Score for Medical Rehabilitation Patients (NQF #2633).
- Application of IRF Functional Outcome Measure: Change in Mobility Score for Medical Rehabilitation Patients (NQF #2634).
- Application of IRF Functional Outcome Measure: Discharge Self-Care Score for Medical Rehabilitation Patients (NQF #2635).
- Application of IRF Functional Outcome Measure: Discharge Mobility Score for Medical Rehabilitation Patients (NQF #2636).

The measures are described in more detail below.

(1) Replacing the Current Pressure Ulcer Quality Measure, Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short Stay) (NQF #0678), with a Modified Pressure Ulcer Measure, Changes in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury

(a) Measure Background

In the FY 2018 SNF PPS proposed rule (82 FR 21045 through 21049), we proposed to remove the current pressure ulcer measure, Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short Stay) (NQF #0678) from the SNF QRP measure set and replace it with a modified version of that measure, Changes in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury, beginning with the FY 2020 SNF QRP. The change in the measure name is to reduce confusion about the new modified measure. The modified version differs from the current version of the measure because it includes new or worsened unstageable pressure ulcers, including deep tissue injuries (DTIs), in the measure numerator. The modified version of the measure would satisfy the IMPACT Act domain of skin integrity and changes in skin integrity.

We note that the technical specifications for the pressure ulcer measure were updated in August 2016 through a subregulatory process to ensure technical alignment of the SNF measure specifications with the LTCH, IRF, and HH specifications. The technical updates were added to ensure clarity in how the measure is calculated, and to avoid possible over counting of pressure ulcers in the numerator. We corrected the technical specifications to mitigate the risk of over counting new or worsened pressure ulcers and to reflect the actual unit of analysis as finalized in the rule, which is a stay (Medicare Part A stay) for SNF QRP, consistent with the IRF, and LTCH QRPs, rather than an episode (which could include multiple stays) as is used in the case of Nursing Home Compare. Thus, we updated the SNF measure specifications to reflect all resident stays, rather than the most-recent episode in a quarter, which is comprised of one or more stays in that measure calculation. Also, to ensure alignment, we corrected our specifications to ensure that healed wounds are not incorrectly captured in the measure. Further, we corrected the specifications to ensure the exclusion of residents who expire during their SNF stay. The SNF specifications can be reviewed on our Web site 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.*

(b) Measure Importance

As described in the FY 2016 SNF PPS final rule (80 FR 46433), pressure ulcers are high-cost adverse events and an important measure of quality. For information on the history and rationale for the relevance, importance, and applicability of having a pressure ulcer measure in the SNF QRP, we refer readers to the FY 2016 SNF PPS final rule (80 FR 46433 through 46434).

We proposed to adopt a modified version of the current pressure ulcer measure because unstageable pressure ulcers, including DTIs, are similar to Stage 2, Stage 3, and Stage 4 pressure ulcers in that they represent poor outcomes, are a serious medical condition that can result in death and disability, are debilitating and painful, and are often an avoidable outcome of medical care.[8] [9] [10] [11] [12] [13] Studies show that most pressure ulcers can be avoided and can also be healed in acute, post-acute, and long-term care settings with appropriate medical care.[14]

Furthermore, some studies indicate that DTIs, if managed using appropriate care, can be resolved without deteriorating into a worsened pressure ulcer.[15] [16] While DTIs are a subset of unstageable pressure ulcers, we collect DTI data elements separately and analyze them both separately and with other unstageable pressure ulcer item categories in our analysis below. We note that DTIs are categorized as a type of unstageable pressure ulcer on the MDS and other post-acute care item sets.

While there are few studies that provide information regarding the incidence of unstageable pressure ulcers in PAC settings, an analysis conducted by a contractor suggests the incidence of unstageable pressure ulcers varies according to the type of unstageable pressure ulcer and setting.[17] This analysis examined the national incidence of new unstageable pressure ulcers in SNFs at discharge compared with admission using SNF discharges from January through December 2015. The contractor found a national incidence of 0.40 percent of new unstageable pressure ulcers due to slough and/or eschar, 0.02 percent of new unstageable pressure ulcers due to non-removable dressing/device, and 0.57 percent of new DTIs. In addition, an international study spanning the time period 2006 to 2009, provides some evidence to suggest that the

[8] Casey, G. (2013). ''Pressure ulcers reflect quality of nursing care.'' *Nurs N Z* 19(10):20–24.

[9] Gorzoni, M.L. and S.L. Pires (2011). ''Deaths In nursing homes.'' *Rev Assoc Med Bras* 57(3):327–331.

[10] Thomas, J.M., et al. (2013). ''Systematic review: health-related characteristics of elderly hopitalized adults and nursing home residents associated with short-term mortality.'' *J Am Geriatr Soc* 61(6): 902–911.

[11] White-Chu, E.F., et al. (2011). ''Pressure ulcers in long-term care.'' *Clin Geriatr Med* 27(2):241–258.

[12] Bates-Jensen BM. Quality indicators for prevention and management of pressure ulcers in vulnerable elders. *Ann Int Med.* 2001;135 (8 Part 2), 744–51.

[13] Bennet, G, Dealy, C Posnett, J (2004). The cost of pressure ulcers in the UK, *Age and Aging,* 33(3):230–235.

[14] Black, Joyce M., et al. ''Pressure ulcers: avoidable or unavoidable? Results of the national pressure ulcer advisory panel consensus conference.'' *Ostomy-Wound Management* 57.2 (2011): 24.

[15] Sullivan, R. (2013). A Two-year Retrospective Review of Suspected Deep Tissue Injury Evolution in Adult Acute Care Patients. Ostomy Wound Management 59(9) *http://www.o-wm.com/article/two-year-retrospective-review-suspected-deep-tissue-injury-evolution-adult-acute-care-patien.*

[16] Posthauer, ME, Zulkowski, K. (2005). Special to OWM: The NPUAP Dual Mission Conference: Reaching Consensus on Staging and Deep Tissue Injury. Ostomy Wound Management 51(4) *http://www.o-wm.com/content/the-npuap-dual-mission-conference-reaching-consensus-staging-and-deep-tissue-injury.*

[17] Final Measure Specifications for SNF QRP Quality Measures and Standardized Resident Assessment Data Elements, 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.*

proportion of pressure ulcers identified as DTI has increased over time.[18]

The inclusion of unstageable pressure ulcers, including DTIs, in the numerator of this measure is expected to increase measure scores and variability in measure scores, thereby improving the ability to discriminate among poor- and high-performing SNFs. In the currently implemented pressure ulcer measure, Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short Stay) (NQF #0678), analysis using data from Quarter 4 2015 through Quarter 3 2016 reveals that the SNF mean score is 1.75 percent; the 25th and 75th percentiles are 0.0 percent and 2.53 percent, respectively; and 29.11 percent of facilities have perfect scores. In the measure, Changes in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury, during the same timeframe, the SNF mean score is 2.58 percent; the 25th and 75th percentiles are 0.65 percent and 3.70 percent, respectively; and 20.32 percent of facilities have perfect scores.

(c) Stakeholder Feedback

Our measure development contractor sought input from subject matter experts, including Technical Expert Panels (TEPs), over the course of several years on various skin integrity topics and specifically those associated with the inclusion of unstageable pressure ulcers, including DTIs. Most recently, on July 18, 2016, a TEP convened by our measure development contractor provided input on the technical specifications of this quality measure, including the feasibility of implementing the proposed measure's updates related to the inclusion of unstageable ulcers, including DTIs, across PAC settings. The TEP supported the updates to the measure across PAC settings, including the inclusion in the numerator of unstageable pressure ulcers due to slough and/or eschar that are new or worsened, new unstageable pressure ulcers due to a non-removable dressing or device, and new DTIs. The TEP recommended supplying additional guidance to providers regarding each type of unstageable pressure ulcer. This support was in agreement with earlier TEP meetings, held on June 13, and November 15, 2013, which had recommended that CMS update the specifications for the pressure ulcer measure to include unstageable pressure ulcers in the numerator.[19] [20] Exploratory data analysis conducted by our measure development contractor suggests that the addition of unstageable pressure ulcers, including DTIs, will increase the observed incidence and variation in the rate of new or worsened pressure ulcers at the facility level, which may improve the ability of the proposed quality measure to discriminate between poor- and high-performing facilities.

We solicited stakeholder feedback on this proposed measure by means of a public comment period held from October 17 through November 17, 2016. In general, we received considerable support for the proposed measure. A few commenters supported all of the changes to the current pressure ulcer measure that resulted in the measure, with one commenter noting the significance of the work to align the pressure ulcer quality measure specifications across the PAC settings. Many commenters supported the inclusion of unstageable pressure ulcers due to slough/eschar, due to non-removable dressing/device, and DTIs in the quality measure. Other commenters did not support the inclusion of DTIs in the quality measure because they stated that there is no universally accepted definition for this type of skin injury.

The public comment summary report for the proposed 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*. This summary includes further detail about our responses to various concerns and ideas stakeholders raised at that time.

The NQF-convened Measures Application Partnership (MAP) Post-Acute Care/Long-Term Care (PAC/LTC) Workgroup met on December 14 and 15, 2016, and provided input to us about this measure. The workgroup provided a recommendation of ''support for rulemaking'' for use of the measure in the SNF QRP. The MAP Coordinating Committee met on January 24 and 25, 2017, and provided a recommendation of ''conditional support for rulemaking'' for use of the proposed measure in the SNF QRP. The MAP's conditions of support include that, as a part of measure implementation, CMS provide guidance on the correct collection and calculation of the measure result, as well as guidance on public reporting Web sites explaining the impact of the specification changes on the measure result. The MAP's conditions also specify that CMS continue analyzing the proposed measure to investigate unexpected results reported in public comment. We intend to fulfill these conditions by offering additional training opportunities and educational materials in advance of public reporting, and by continuing to monitor and analyze the proposed measure. More information about the MAP's recommendations for this measure is available at *http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=84452*.

We reviewed the NQF's consensus endorsed measures and were unable to identify any NQF-endorsed pressure ulcer quality measures for PAC settings that are inclusive of unstageable pressure ulcers. There are related measures, but after careful review, we determined these measures are not applicable for use in SNFs based on the populations addressed or other aspects of the specifications. We are unaware of any other such quality measures that have been endorsed or adopted by another consensus organization for the SNF setting. Therefore, based on the evidence discussed above, we proposed to adopt the quality measure entitled, Changes in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury, for the SNF QRP beginning with the FY 2020 SNF QRP. We plan to submit the proposed measure to the NQF for endorsement consideration as soon as feasible.

(d) Data Collection

The data for this quality measure would be collected using the MDS, which is currently submitted by SNFs through the Quality Improvement and Evaluation System (QIES) Assessment Submission and Processing (ASAP) System. The proposed standardized resident assessment data applicable to this measure that must be reported by SNFs for admissions as well as discharges occurring on or after October

[18] VanGilder, C, MacFarlane, GD, Harrison, P, Lachenbruch, C, Meyer, S (2010). The Demographics of Suspected Deep Tissue Injury in the United States: An Analysis of the International Pressure Ulcer Prevalence Survey 2006–2009. Advances in Skin & Wound Care. 23(6): 254–261.

[19] Schwartz, M., Nguyen, K.H., Swinson Evans, T.M., Ignaczak, M.K., Thaker, S., and Bernard, S.L.: Development of a Cross-Setting Quality Measure for Pressure Ulcers: OY2 Information Gathering, Final Report. Centers for Medicare & Medicaid Services, November 2013. Available: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/Downloads/Development-of-a-Cross-Setting-Quality-Measure-for-Pressure-Ulcers-Information-Gathering-Final-Report.pdf*.

[20] Schwartz, M., Ignaczak, M.K., Swinson Evans, T.M., Thaker, S., and Smith, L.: The Development of a Cross-Setting Pressure Ulcer Quality Measure: Summary Report on November 15, 2013, Technical Expert Panel Follow-Up Webinar. Centers for Medicare & Medicaid Services, January 2014. Available: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/Downloads/Development-of-a-Cross-Setting-Pressure-Ulcer-Quality-Measure-Summary-Report-on-November-15-2013-Technical-Expert-Pa.pdf*.

1, 2018 is described in section III.D.2. of this final rule. SNFs are already required to complete unstageable pressure ulcer data elements on the MDS. While the inclusion of unstageable wounds in the proposed measure results in a measure calculation methodology that is different from the methodology used to calculate the current pressure ulcer measure, the data elements needed to calculate the proposed measure are already included in the MDS. In addition, this proposed measure will further standardize the data elements used in risk adjustment of this measure. Our proposal to eliminate duplicative data elements will result in an overall reduced reporting burden for SNFs for the proposed measure.

To view the updated MDS, with the proposed changes, we refer to the reader to *https://www.cms.gov/medicare/quality-initiatives-patient-assessment-instruments/nursinghomequalityinits/mds30raimanual.html*. For more information on MDS submission using the QIES ASAP System, we refer readers to *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/NursingHomeQualityInits/NHQIMDS30TechnicalInformation.html*.

For technical information about this proposed measure, including information about the measure calculation and the standardized resident assessment data elements used to calculate this measure, we refer readers to the document titled, *Final Measure Specifications for SNF QRP Quality Measures and Standardized Resident Assessment Data Elements,* 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 proposed that SNFs begin reporting the proposed pressure ulcer measure, Changes in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury, which will replace the current pressure ulcer measure, with data collection beginning October 1, 2018 for admissions as well as discharges.

We sought public comment on our proposal to replace the current pressure ulcer measure, Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short Stay) (NQF #0678), with a modified version of that measure, entitled Changes in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury, beginning with the FY 2020 SNF QRP. A discussion of these comments, along with our responses, appears below.

Comment: Many commenters supported the proposed replacement of the current pressure ulcer measure, the Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short Stay) (NQF #0678), with a modified version of that measure, entitled Changes in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury. Commenters recognized that the proposed measure will meet the requirements of the IMPACT Act for the Skin Integrity and Changes in Skin Integrity domain. Commenters believed that the revisions identified in the proposed rule will improve on the existing pressure ulcer measure and ensure that the data collected accurately reflects the care and conditions of the SNF patient population. One commenter supported the use of data elements that are already in use in the MDS to reduce reporting burden for providers. Another commenter noted that revisions to quality measures are an important part of ensuring accurate information that is reflective of advances in knowledge and technology, and ensuring that the data reflect the patient population.

Response: We appreciate the commenters' support to replace the current pressure ulcer measure, Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short Stay) (NQF #0678), with a modified version of the measure, Changes in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury to fulfill the requirements of the IMPACT Act. We agree that this proposal will limit regulatory burden and promote high quality care, as the commenters describe.

Comment: A few commenters expressed concerns that the variation in measure scores between facilities could reflect differences in the interpretation of definitions for unstageable pressure ulcers or DTIs, rather than actual differences in quality or care practices. One commenter cautioned that a measure should not be changed to create performance variation, but rather to be consistent with current science or to provide clarity and consistent data collection. The commenters encouraged additional testing of the measure to ensure that it collects accurate data.

Response: We have performed testing to compare the performance of the proposed measure with the existing pressure ulcer/injury measure. Current findings indicate that the measure is both valid and reliable in the SNF, LTCH, and IRF settings.

The reliability and validity of the data elements used to calculate this quality measure have been tested in several ways. Rigorous testing on both reliability and validity of the data elements in the MDS 3.0 provides evidence for the data elements used in the SNF, LTCH, and IRF settings.[21] The MDS 3.0 pilot test showed good reliability, and the results are applicable to the IRF–PAI as well as the LTCH CARE Data Set because the data elements tested are the same as those used in the IRF–PAI and LTCH CARE Data Set. Across pressure ulcer data elements, average gold-standard to gold-standard kappa statistic was 0.905. The average gold-standard to facility-nurse kappa statistic was 0.937. These kappa scores indicate ''almost perfect'' agreement using the Landis and Koch standard for strength of agreement.[22]

To assess the construct validity of this measure, or the degree to which the measure construct measures what it claims or purports to be measuring, our measure contractor sought input from TEPs over the course of several years. Most recently, on July 18, 2016, a TEP supported the inclusion in the numerator of unstageable pressure ulcers due to slough and/or eschar that are new or worsened, new unstageable pressure ulcers/injuries due to a non-removable dressing or device, and new DTIs. The measure testing activities were presented to TEP members for their input on the reliability, validity, and feasibility of this measure change. The TEP members supported the measure construct.

The proposed measure also increased the variability of measures scores between providers, as noted by some commenters. We would like to clarify that the goal of the proposed measure is not to create performance variation where none exists, but rather to better measure existing performance variation. This increased variability of scores between facilities will improve the ability of the measure to distinguish between high- and low-performing facilities.

We will continue to perform reliability and validity testing in compliance with NQF guidelines and the Blueprint for the CMS Measures Management System to ensure that that the measure demonstrates scientific acceptability (including reliability and validity) and meets the goals of the QRP.

[21] Saliba, D., & Buchanan, J. (2008, April). Development and validation of a revised nursing home assessment tool: MDS 3.0. Contract No. 500–00–0027/Task Order #2. Santa Monica, CA: Rand Corporation. Retrieved from *http://www.cms.hhs.gov/NursingHomeQualityInits/Downloads/MDS30FinalReport.pdf*.

[22] Landis, R., & Koch, G. (1977, March). The measurement of observer agreement for categorical data. Biometrics 33(1), 159–174.

Finally, as with all measure development and implementation, we will provide training and guidance prior to implementation of the measure to promote consistency in the interpretation of the measure.

Comment: Commenters requested further training and guidance in completing the M0300 data element that will be used to calculate the proposed quality measure. One commenter stated that confusion exists related to worsening of pressure ulcers, unstageable pressure ulcers due to slough or eschar, and the concept of ''present on admission''. One commenter stated that the use of these data elements would require SNFs to calculate the number of new or worsened pressure ulcers by subtracting those present on admission. Some commenters stated that the modified measure may be difficult for providers to capture because they are being asked to report on a different data element.

Response: The measure will be calculated using data reported on the M0300 data element collected at discharge, which only requires SNFs to report the number of pressure ulcers for each stage (including stages 2, 3, and 4, unstageable due to slough and/or eschar, unstageable due to non-removable dressing/device, and DTIs), and of those, the number that were present on admission. The M0300 data element currently exists on the MDS, and the current MDS RAI Manual, as well as prior versions of the Manual, include guidance about how to complete the data element, including unstageable pressure ulcers and pressure ulcers that are present on admission. The MDS RAI Manual can be found at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/NursinghomeQualityInits/MDS30RAIManual.html.*

Comment: We received several comments regarding the inclusion of unstageable pressure ulcers in the proposed measure. One commenter specifically supported the inclusion of these types of pressure ulcers. Other commenters did not support the inclusion of unstageable pressure ulcers, in the quality measure as proposed, and encouraged further testing. Some commenters stated that there is a lack of clear definition of pressure ulcers included in this measure, and that those definitions may be too subjective to get reliable data. Commenters also requested that we provide training opportunities and educational materials prior to the implementation of this measure.

Response: We appreciate the support we have received regarding the inclusion of unstageable pressure ulcers, including DTIs, in the proposed quality measure. We believe that the inclusion of unstageable pressure ulcers in the measure will result in a fuller picture of quality to residents and families, and lead to further quality improvement efforts that will advance patient safety by reducing the rate of facility acquired pressure ulcers at any stage. We would like to clarify that the definitions of pressure ulcers are adapted from the National Pressure Ulcer Advisory Panel (NPUAP), and are standardized across all PAC settings. These definitions are universally accepted, objective, and considered to be the gold-standard definition by national and international stakeholders such as the NPUAP, European Pressure Ulcer Advisory Panel (EPUAP), Wound, Ostomy and Continence Nurses Society (WOCN), amongst others. As a result, the use of these universally accepted definitions of pressure ulcers furthers our commitment to ensuring that all quality measures implemented in the QRP meet the testing goals of the QRP.

To provide greater clarity about the definitions of different types of unstageable pressure ulcers and how to code them on the MDS, we are currently engaged in multiple educational efforts. These include training events, updates to the manuals and training materials, and responses to Help Desk questions to promote understanding and proper coding of these data elements. We will continue to engage in these training activities prior to implementation of the proposed measure.

Comment: One commenter specifically supported the new measure and the specific inclusion of DTIs, and stressed the importance and impact of such change in increasing the number of pressure ulcers captured. The commenter stated that it would be important to note the impact on the Five Star Quality Rating System. This commenter also noted that some DTIs can also evolve or worsen, despite being managed with appropriate care. Other commenters did not support the inclusion of DTIs in the measure. These commenters stated that there is not a universally accepted definition of DTIs, and that DTIs are commonly misdiagnosed, which could lead to surveillance bias.

Response: We appreciate the comments regarding the inclusion of DTIs in the proposed quality measure. DTIs are often an avoidable outcome of medical care, are debilitating and painful, and can result in death and/or disability, similar to Stage 2, Stage 3 and Stage 4 pressure ulcers. While some DTIs may worsen, studies indicate that many DTIs, if managed using appropriate care, can be resolved without deteriorating into a worsened pressure ulcer. Therefore, we believe that the inclusion of DTIs in the proposed quality measure is essential to be able to accurately reflect the number of these types of pressure injuries and to provide the appropriate patient care. Further, we believe that it is important to do a thorough assessment on every patient in each PAC setting, including a thorough skin assessment documenting the presence of any pressure ulcers or injuries of any kind, including DTIs. We agree that it is important to conduct thorough and consistent assessments to avoid the possibility of surveillance bias.

When considering the addition of DTIs to the measure numerator, we convened cross-setting TEPs in June and November 2013, and obtained input from clinicians, experts, and other stakeholders. An additional cross-setting TEP convened by our measure development contractor in July 2016 also supported the recommendation to include unstageable pressure ulcers, including DTIs, in the numerator of the quality measure. Given DTIs' potential impact on mortality, morbidity, and quality of life, it may be detrimental to the quality of care to exclude DTIs from a pressure ulcer quality measure.

We do not intend to include the proposed measure in the Five Star Quality Rating System calculations.

Comment: Several commenters recommended that we attain NQF endorsement of the Changes in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury measure prior to implementation.

Response: 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 consideration as soon as feasible.

Comment: Several commenters noted that there is a difference in the denominator across settings in terms of which payer sources (Medicare Part A or Medicare Advantage) are included in the measure. Commenters recommended that we ensure that common denominators are used when displaying this measure for quality comparison purposes. One commenter stated that there is an IMPACT Act mandate to implement ''interoperable measures'' across PAC settings.

Response: We recognize that data is currently collected from different payer sources for each PAC setting. We believe

that quality care is best assessed through the collection of data from all patients, and strive to include the largest possible patient population in the measure denominator. For this reason, we do not seek to limit the denominator in each setting based on the data currently available in other settings (that is, limiting every setting denominator to Medicare Part A patients). Regarding the concern that different patient population denominators are misleading to consumers and providers, we seek to clarify the intent and use of this quality measure through rulemaking, provider training, and ongoing communication with stakeholders. Ongoing communication includes the posting of measure specifications and communication accompanying public reporting. Further, we will take into consideration the expansion of the SNF QRP to include all payer sources through future rulemaking.

The Changes in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury measure is harmonized across all PAC settings and uses standardized resident assessment data as required by the IMPACT Act. Further, we would like to clarify that the M0300 data element used to calculate this measure is standardized across all PAC settings, enabling interoperability. This standardization and interoperability of data elements allows for the exchange of information among PAC providers and other providers to whom this data is applicable. We refer readers to the measure specifications, which describe the specifications for the measure in PAC settings, *Final Specifications for SNF QRP Quality Measures and Standardized Resident Assessment Data Elements,* 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.*

Comment: One commenter indicated support for our efforts to standardize data elements across PAC settings and encouraged further standardization of coding instructions across settings. The commenter specifically noted that coding guidance surrounding Kennedy Ulcers seems to differ between the LTCH and SNF manuals. The commenter urged us to thoroughly review all manuals to ensure standardization of coding guidance and instructions.

Response: The LTCH QRP Manual Version 3.0 instructs LTCHS to not count Kennedy ulcers in the pressure ulcer data elements. The MDS RAI Manual Version 1.14 provides guidance regarding the etiology of ulcers that should be reported in the data elements, but does not provide specific guidance on Kennedy ulcers. The guidance in the two manuals differs in order to be specific to each setting. Although the guidance is tailored to be most applicable to each setting, the data elements are standardized. Therefore, we do not expect this tailored guidance to add variation to the measure outcome or to the standardized resident assessment data.

Comment: A few commenters noted that SNF performance scores on the proposed measure are likely to differ from performance scores on the currently implemented pressure ulcer measure, Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short Stay) (NQF #0678). They recommended development of educational materials for the public to explain the perceived shifts in performance.

Response: We appreciate commenters' concerns about differences in performance scores between the two measures and the possibility of misinterpretation. While the proposed measure will not be directly comparable to the existing measure, it is expected to provide an improved measure of quality moving forward since it will more accurately capture the number of new and worsened pressure ulcers and include unstageable pressure ulcers. Further information and training will be provided to providers as well as consumers regarding how to interpret scores on the proposed measure, to avoid any possible confusion between the proposed measure and the existing measure.

Comment: One commenter suggested that we include additional risk factors in the proposed measure for populations that may be compromised physically, such as the ventilator-dependent population, and to include factors such as whether the resident experienced a hospital stay, was in the emergency department for an extended period of time, was on a stretcher for an extended period of time, was receiving palliative care, and other hospital factors that may lead to the development of pressure ulcers. The commenter also recommended that social risk factors be accounted for in the quality measure. One commenter stated that the proposed measure should be properly risk adjusted.

Response: The proposed quality measure would be risk adjusted for functional mobility admission performance, bowel continence, diabetes mellitus or peripheral vascular disease/peripheral arterial disease, and low body mass index in each of the four settings. This risk adjustment methodology is described further in the *Final Specifications for SNF QRP Quality Measures and Standardized Resident Assessment Data Elements,* 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.* As with our measure modification and evaluation processes, we will continue to analyze this measure, specifically assessing the addition of variables to the risk adjustment model, and testing the inclusion of other risk factors as additional risk adjustors. This continued refinement of the risk adjustment models will 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. Our approach to using social risk factors for risk adjustment is further described in section III.D.2.B.1 of this final rule.

Comment: One commenter requested clarification regarding the proposed measure and the population it is applied to, stating that the long stay pressure ulcer quality measure and short stay pressure ulcer quality measure appear to be combined into a single measure.

Response: The proposed measure, Changes in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury, is distinct from both the Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short-Stay) Measure (NQF #0678) and the Percent of High Risk Residents with Pressure Ulcers (Long Stay) Measure (NQF #0679). There are several key differences between these measures and the programs they are used in. The long-stay measure, Percent of High-Risk Residents with Pressure Ulcers (NQF #0679), measures the percent of residents with one or more conditions indicating high risk to develop pressure ulcers (impaired bed mobility or transfer, comatose, or malnutrition/risk of malnutrition) with any pressure ulcers. This measure is used in the Nursing Home Quality Initiative (NHQI) and reported on Nursing Home Compare. Conversely, the short-stay measure, Percent of Residents with Pressure Ulcers that are New or Worsened (short-stay) (NQF #0678), currently used in used in the SNF QRP, assesses the percentage of residents who develop new pressure ulcers or have existing

pressure ulcers worsen over their course of stay in a PAC facility.

The short stay measure does not include unstageable pressure ulcers in the numerator. The measure is used in the NHQI and reported on Nursing Home Compare, and is also currently applied to SNF residents for the SNF QRP.

We reviewed both the short stay and long stay measures for suitability, but the short stay measure does not include unstageable pressure ulcers in the numerator, as described above, and the long stay measure was determined to not be applicable for use in SNFs due to the populations addressed. The proposed measure is to be applied to the SNF population, which comprises residents who are receiving skilled nursing services. This measure includes new or worsened pressure ulcers that are numerically staged or unstageable, and is standardized across the PAC settings. Further information about the specifications of this measure can be found 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.*

Final Decision: After consideration of the public comments we received, we are finalizing our proposal to remove the current pressure ulcer measure, Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short Stay) (NQF #0678), from the SNF QRP measure set and to replace it with a modified version of that measure, entitled Changes in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury, for the SNF QRP with an implementation date of October 1, 2018.

(2) Functional Outcome Measures

In the FY 2018 SNF PPS proposed rule (82 FR 21047 through 21057) we proposed for the SNF QRP four measures that we are specifying under section 1899B(c)(1) of the Act for the purposes of meeting the functional status, cognitive function, and changes in function and cognitive function domain: (1) Application of the IRF Functional Outcome Measure: Change in Self-Care Score for Medical Rehabilitation Patients (NQF #2633); (2) Application of the IRF Functional Outcome Measure: Change in Mobility Score for Medical Rehabilitation Patients (NQF #2634); (3) Application of the IRF Functional Outcome Measure: Discharge Self-Care Score for Medical Rehabilitation Patients (NQF #2635); and (4) Application of the IRF Functional Outcome Measure: Discharge Mobility Score for Medical Rehabilitation Patients (NQF #2636). We finalized the same functional outcome measures for the IRF QRP in the FY 2016 IRF PPS final rule (80 FR 47111 through 47117). These measures are: (1) IRF Functional Outcome Measure: Change in Self-Care for Medical Rehabilitation Patients (NQF #2633); (2) IRF Functional Outcome Measure: Change in Mobility Score for Medical Rehabilitation (NQF #2634); (3) IRF Functional Outcome Measure: Discharge Self-Care Score for Medical Rehabilitation Patients (NQF #2635); and (4) IRF Functional Outcome Measure: Discharge Mobility Score for Medical Rehabilitation Patients (NQF #2636). We believe these measures satisfy section 1899B(c)(1)(A) of the Act because they address functional status, cognitive function, and changes in function and cognitive function domain. We intend to propose functional outcome measures for the home health and long-term care hospital settings in the future.

In developing these SNF functional outcome quality measures, we sought to build on our cross-setting function work by leveraging data elements currently collected in the MDS section GG, which would minimize additional data collection burden while increasing the feasibility of cross-setting item comparisons.

SNFs provide skilled services, such as skilled nursing or therapy services. Residents receiving care in SNFs include those whose illness, injury, or condition has resulted in a loss of function, and for whom rehabilitative care is expected to help regain that function. Treatment goals may include fostering residents' ability to manage their daily activities so that they can complete self-care and mobility activities as independently as possible, and, if feasible, return to a safe, active, and productive life in a community-based setting. Given that the primary goal of many SNF residents is improvement in function, SNF clinicians assess and document residents' functional status at admission and at discharge to evaluate the effectiveness of the rehabilitation care provided to individual residents and the SNF's effectiveness.

Examination of SNF data shows that SNF treatment practices directly influence resident outcomes. For example, therapy services provided to SNF residents have been found to be correlated with the functional improvement that SNF residents achieve (that is, functional outcomes).[23] Several studies found patients' functional outcomes vary based on treatment by physical and occupational therapists. Specifically, therapy was associated with significantly greater odds of improving mobility and self-care functional independence,[24] shorter length of stay,[25] and a greater likelihood of discharge to community.[26] Furthermore, Jung et al.[27] found that an additional hour of therapy treatment per week was associated with approximately a 3.1 percentage-point increase in the likelihood of returning to the community among residents with a hip fracture. Achieving these targeted resident outcomes, including improved self-care and mobility functional independence, reduced length of stay, and increased discharges to the community, is a core goal of SNFs.

Among SNF residents receiving rehabilitation services, the amount of treatment received can vary. For example, the amount of therapy treatment provided varies by type (that is, for-profit versus not-for-profit) and facility location (that is, urban versus rural).[28] [29]

Measuring residents' functional improvement across all SNFs on an ongoing basis would permit identification of SNF characteristics, such as ownership types or locations, associated with better or worse resident risk adjusted outcomes and thus help SNFs optimally target quality improvement efforts.

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[23] Jette, D. U., R. L. Warren, & C. Wirtalla. (2005). The relation between therapy intensity and outcomes of rehabilitation in skilled nursing facilities. Archives of Physical Medicine and Rehabilitation, 86 (3), 373–9.

[24] Lenze, E.J., Host, H.H., Hildebrand, M.W., Morrow-Howell, N., Carpenter, B., Freedland, K.E., . . . & Binder, E.F. (2012). Enhanced medical rehabilitation increases therapy intensity and engagement and improves functional outcomes in post acute rehabilitation of older adults: a randomized-controlled trial. Journal of the American Medical Directors Association, 13(8), 708–712.

[25] Medicare Payment Advisory Commission (US). (2016). Report to the Congress: Medicare payment policy. Medicare Payment Advisory Commission.

[26] Cary, M.P., Pan, W., Sloane, R., Bettger, J.P., Hoenig, H., Merwin, E.I., & Anderson, R.A. (2016). Self-Care and Mobility Following Postacute Rehabilitation for Older Adults with Hip Fracture: A Multilevel Analysis. Archives of Physical Medicine and Rehabilitation, 97(5), 760–771.

[27] Jung, H.Y., Trivedi, A.N., Grabowski, D.C., & Mor, V. (2016). Does More Therapy in Skilled Nursing Facilities Lead to Better Outcomes in Patients With Hip Fracture? Physical therapy, 96(1), 81–89.

[28]

[29] Grabowski, D.C., Feng, Z., Hirth, R., Rahman, M., & Mor, V. (2013). Effect of nursing home ownership on the quality of post-acute care: An instrumental variables approach. Journal of Health Economics, 32(1), 12–21.

MedPAC[30] noted that while there was an overall increase in the share of intensive therapy days between 2002 and 2012, the for-profit and urban facilities had higher shares of intensive therapy than not-for-profit facilities and those located in rural areas. Data from 2011 to 2014 indicate that this variation is not explained by patient characteristics, such as activities of daily living, comorbidities and age, as SNF residents with stays in 2011 were more independent on average than the average SNF resident with stays in 2014. Because more intense therapy is associated with more functional improvement for certain beneficiaries, this variation in rehabilitation services supports the need to monitor SNF residents' functional outcomes. Therefore, we believe there is an opportunity for improvement in this area.

In addition, a recent analysis that examined the incidence, prevalence, and costs of common rehabilitation conditions found that back pain, osteoarthritis, and rheumatoid arthritis are the most common and costly conditions affecting more than 100 million individuals and costing more than $200 billion per year.[31] Persons with these medical conditions are admitted to SNFs for rehabilitation treatment.

The use of standardized mobility and self-care data elements would standardize the collection of functional status data, which could improve communication when residents are transferred between providers. Most SNF residents receive care in an acute care hospital prior to the SNF stay, and many SNF residents receive care from another provider after the SNF stay.

Recent research provides empirical support for the risk adjustment variables for these quality measures. In a study of resident functional improvement in SNFs, Wysocki et al.[32] found that several resident conditions were significantly related to resident functional improvement, including cognitive impairment, delirium, dementia, heart failure, and stroke. Also, Cary et al. found that several resident characteristics were significantly related to resident functional improvement, including age, cognitive function, self-care function at admission, and comorbidities.[33]

These outcome-based quality measures could inform SNFs about opportunities to improve care in the area of function and strengthen incentives for quality improvement related to resident function.

We describe each of the four functional outcome quality measures below, and then follow with a discussion of the comments we received.

(a) Application of IRF Functional Outcome Measure: Change in Self-Care Score for Medical Rehabilitation Patients (NQF #2633)

The outcome quality measure, Application of IRF Functional Outcome Measure: Change in Self-Care Score for Medical Rehabilitation Patients (NQF #2633), is an application of the outcome measure finalized in the IRF QRP entitled, IRF Functional Outcome Measure: Change in Self-Care Score for Medical Rehabilitation Patients (NQF #2633). The quality measure estimates the mean risk-adjusted improvement in self-care score between admission and discharge among SNF residents. A summary of the NQF-endorsed quality measure specifications can be accessed on the NQF Web site: *http://www.qualityforum.org/qps/2633.* Detailed specifications for the NQF-endorsed quality measure can be accessed at *http://www.qualityforum.org/ProjectTemplateDownload.aspx?SubmissionID=2633.*

The functional outcome measure, the Application of IRF Functional Outcome Measure: Change in Self-Care Score for Medical Rehabilitation Patients (NQF #2633), requires the collection of admission and discharge functional status data by trained clinicians using standardized patient data elements that assess specific functional self-care activities such as shower/bathe self, dressing upper body and dressing lower body. These self-care items are daily activities that clinicians typically assess at the time of admission and/or discharge to determine residents' needs, evaluate resident progress, and/or prepare residents and families for a transition to home or to another provider. The standardized self-care function data elements are coded using a 6-level rating scale that indicates the resident's level of independence with the activity; higher scores indicate more independence. The outcome quality measure also requires the collection of risk factor data, such as resident functioning prior to the current reason for admission, bladder continence, communication ability and cognitive function, at the time of admission.

The data elements included in the quality measure were originally developed and tested as part of the PAC PRD version of the Continuity Assessment Record and Evaluation (CARE) Item Set,[34] which was designed to standardize assessment of patients' and residents' status across acute and post-acute providers, including IRFs, SNFs, HHAs and LTCHs. The development of the CARE Item Set and a description and rationale for each item is described in a report entitled ''The Development and Testing of the Continuity Assessment Record and Evaluation (CARE) Item Set: Final Report on the Development of the CARE Item Set: Volume 1 of 3.'' [35] Reliability and validity testing were conducted as part of CMS' Post-Acute Care Payment Reform Demonstration, and we concluded that the functional status items have acceptable reliability and validity. A description of the testing methodology and results are available in several reports, including the report entitled ''The Development and Testing of the Continuity Assessment Record And Evaluation (CARE) Item Set: Final Report On Reliability Testing: Volume 2 of 3'' [36] and the report entitled ''The Development and Testing of The Continuity Assessment Record And Evaluation (CARE) Item Set: Final Report on Care Item Set and Current Assessment Comparisons: Volume 3 of 3.'' [37] The reports are available on CMS' Post-Acute Care Quality Initiatives Web page at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/CARE-Item-Set-and-B-CARE.html.*

[30] Medicare Payment Advisory Commission (US). (2016). Report to the Congress: Medicare payment policy. Medicare Payment Advisory Commission.

[31] Ma V.Y., Chan L., & Carruthers K.J. (2014). Incidence, Prevalence, Costs, and Impact on Disability of Common Conditions Requiring Rehabilitation in the United States: Stroke, Spinal Cord Injury, Traumatic Brain Injury, Multiple Sclerosis, Osteoarthritis, Rheumatoid Arthritis, Limb Loss, and Back Pain. Archives of Physical Medicine and Rehabilitation, 95(5), 986–995.

[32] Wysocki, A., Thomas, K.S., & Mor, V. (2015). Functional Improvement Among Short-Stay Nursing Home Residents in the MDS 3.0. Journal of the American Medical Directors Association, 16(6), 470–474. *http://doi.org/10.1016/j.jamda.2014.11.018.*

[33] Cary, M.P., Pan, W., Sloane, R., Bettger, J.P., Hoenig, H., Merwin, E.I., & Anderson, R.A. (2016). Self-Care and Mobility Following Postacute Rehabilitation for Older Adults With Hip Fracture: A Multilevel Analysis. Archives of Physical Medicine and Rehabilitation, 97(5), 760–771.

[34] Barbara Gage et al., ''The Development and Testing of the Continuity Assessment Record and Evaluation (CARE) Item Set: Final Report on the Development of the CARE Item Set'' (RTI International, 2012).

[35] Barbara Gage et al., ''The Development and Testing of the Continuity Assessment Record and Evaluation (CARE) Item Set: Final Report on the Development of the CARE Item Set'' (RTI International, 2012).

[36] Ibid.

[37] Ibid.

(i) Stakeholder Input

A cross-setting function TEP convened by our measure development contractor on September 9, 2013 provided input on the initial technical specifications of this quality measure, Application of IRF Functional Outcome Measure: Change in Self-Care Score for Medical Rehabilitation Patients (NQF #2633). The TEP was supportive of the implementation of this measure and supported CMS's efforts to standardize patient/resident assessment data elements. The TEP summary report is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

The MAP met on December 14 and 15, 2015, and provided input on the measure, Application of IRF Functional Outcome Measure: Change in Self-Care Score for Medical Rehabilitation Patients (NQF #2633) for use in the SNF QRP. The MAP recognized that this quality outcome measure is an adaptation of a currently endorsed measure for the IRF population, and encouraged continued development to ensure alignment of this measure across PAC settings. The MAP noted there should be some caution in the interpretation of measure results due to resident differentiation between facilities. The MAP also noted possible duplication as the MDS already includes function data elements. We note that the data elements for the measure are similar, but not the same as the existing MDS Section G function data elements. The data elements for the measure include those that are the standardized patient assessment data for functional status under section 1899B(b)(1)(B)(i) of the Act. The MAP also stressed the importance of considering burden on providers when measures are considered for implementation. The MAP's overall recommendation was for ''encourage further development.'' More information about the MAP's recommendations for this measure is available at *http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=81593.*

Since the MAP's review and recommendation for further development, we have continued to develop this measure by soliciting input via a TEP, providing a public comment opportunity, and providing an update on measure development to the MAP via the feedback loop. More specifically, our measure development contractor convened a SNF-specific function TEP on May 5, 2016, to provide further input on the technical specifications of this quality measure by reviewing the IRF specifications and the specifications of competing and related function quality measures. Overall, the TEP was supportive of the measure and supported our efforts to standardize patient assessment data elements. The SNF-specific function TEP summary report is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

We also solicited stakeholder feedback on the development of this measure by means of a public comment period that was open from October 7, 2016, until November 4, 2016. There was general support of the measure concept and the importance of functional improvement. Comments on the measure varied, with some commenters supportive of the measure, while others were either not in favor of the measure, or in favor of suggested potential modifications to the measure specifications. 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.*

Further, we engaged with stakeholders when we presented an update on the development of this quality measure to the MAP on October 19, 2016, during a MAP feedback loop meeting. Slides from that meeting are available at *http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=83640.*

(ii) Competing and Related Measures and Measure Justification

During the development of this proposed functional outcome measure, we have monitored and reviewed NQF-endorsed measures that are competing and/or related to the proposed quality measures. We identified six competing and related quality measures focused on self-care functional improvement for residents in the SNF setting entitled: (1) CARE: Improvement in Self Care (NQF #2613); (2) Functional Change: Change in Self-Care Score for Skilled Nursing Facilities (NQF #2769); (3) Functional Status Change for Patients with Shoulder Impairments (NQF #0426); (4) Functional Status Change for Patients with Elbow, Wrist and Hand Impairments (NQF #0427); (5) Functional Status Change for Patients with General Orthopedic Impairments (NQF #0428); and (6) Change in Daily Activity Function as Measures by the AM–PAC (NQF #0430). We reviewed the technical specifications for these six quality measures and compared these specifications to those of our outcome-based quality measure, the Application of IRF Functional Outcome Measure: Change in Self-Care Score for Medical Rehabilitation Patients (NQF #2633), and have noted the following differences in the technical specifications: (1) The number of risk adjustors and variance explained by these risk adjustors in the regression models; (2) the use of functional assessment items that were developed and tested for cross-setting use; (3) the use of items that are already on the MDS 3.0 and what this means for burden; (4) the handling of missing functional status data; and (5) the use of exclusion criteria that are baseline clinical conditions. We describe these key specifications of the proposed outcome measure, Application of IRF Functional Outcome Measure: Change in Self-Care Score for Medical Rehabilitation Patients (NQF #2633), in detail below.

Our literature review, input from technical expert panels, public comment feedback, and data analyses demonstrated the importance of adequate risk adjustment of admission case mix factors for functional outcome measures. Inadequate risk adjustment of admission case mix factors may lead to erroneous conclusions about the quality of care delivered within the facility, and thus is a potential threat to the validity of a quality measure that examines outcomes of care, such as functional outcomes. The quality measure, the Application of IRF Functional Outcome Measure: Change in Self-Care Score for Medical Rehabilitation Patients (NQF #2633) risk adjusts for more than 60 risk factors, explaining approximately 25 percent of the variance in change in function, and includes all of the following risk factors: prior functioning, prior device use, age, functional status at admission, primary diagnosis, and comorbidities. These risk factors are key predictors of functional performance and should be accounted for in any facility-level comparison of functional outcomes.

Another key feature of the measure, the Application of IRF Functional Outcome Measure: Change in Self-Care Score for Medical Rehabilitation Patients (NQF #2633), is that it uses the functional assessment data elements and the associated rating scale that were developed and tested for cross-setting

use. The measure uses functional assessment items from the CARE Item Set, which were developed and tested as part of the PAC–PRD between 2006 and 2010. The items were designed to build on the existing science for functional assessment instruments, and included a review of the strengths and limitations of existing functional assessment instruments. An important strength of the standardized function items from the CARE instrument is that they allow comparison and tracking of patients' and residents' functional outcomes as they move across post-acute settings. Specifically, the CARE Item Set was designed to standardize assessment of patients' status across acute and post-acute settings, including SNFs, IRFs, LTCHs, and HHAs. The risk-adjustors for various setting-specific versions of this measure differ by the inclusion of adjustors such as comorbidities in the IRF measure. However, we believe that the differences in risk adjustment will not hinder future comparability across settings. Agencies such as MedPAC have supported a coordinated approach to measurement across settings using standardized patient data elements.

A third important consideration is that some of the data elements associated with the measure are already included on the MDS in section GG, because we adopted a cross-setting function process measure in the SNF QRP FY 2016 Final Rule (FR 80 46444 through 46453). Three of the self-care data elements necessary to calculate that quality measure, an Application of the Percent of Long-Term Care Hospital Patient with a Functional Assessment and a Care Plan that Addresses Function (NQF #2631) are used to calculate the quality measure. Provider burden of reporting on multiple items was a key consideration discussed by stakeholders in our recent TEP is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

We believe it is important to include the records of residents with missing functional assessment data when calculating a facility-level functional outcome quality measure for SNFs. The proposed measure, the Application of IRF Functional Outcome Measure: Change in Self-Care Score for Medical Rehabilitation Patients (NQF #2633), incorporates a method to address missing functional assessment data.

We believe certain clinically-defined exclusion criteria are important to specify in a functional outcome quality measure to maintain the validity of the quality measure. Exclusions for the quality measure, Application of IRF Functional Outcome Measure: Change in Self-Care Score for Medical Rehabilitation Patients (NQF #2633), were selected through a review of the literature, input from Technical Expert Panels, and input from the public comment process. The quality measure, Application of IRF Functional Outcome Measure: Change in Self-Care Score for Medical Rehabilitation Patients (NQF #2633) is intended to capture improvement in self-care function from admission to discharge for residents who are admitted with an expectation of functional improvement. Therefore, we exclude residents with certain conditions, for example progressive neurologic conditions, because these residents are typically not expected to improve on self-care skills for activities such as lower body dressing. Furthermore, we exclude residents who are independent on all self-care items at the time of admission, because no improvement in self-care can be measured with the selected set of items by discharge. Including residents with limited expectation for improvement could introduce incentives for SNFs to restrict access to these residents.

We would like to note that our measure developer presented and discussed these technical specification differentiations with TEP members during the May 6, 2016 TEP meeting to obtain TEP input on preferred specifications for valid functional outcome quality measures. The differences in measure specifications and the TEP feedback are presented in the TEP Summary Report, which is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.* Overall, the TEP supported the use of a risk adjustment model that addressed all of the following risk factors: Prior functioning, admission functioning, prior diagnosis and comorbidities. In addition, they supported exclusion criteria that would address functional improvement expectations of residents.

(iii) Data Collection Mechanism

Data for the quality measure, the Application of IRF Functional Outcome Measure: Change in Self-Care Score for Medical Rehabilitation Patients (NQF #2633), would be collected using the MDS, with the submission through the QIES ASAP system. For more information on SNF QRP reporting through the QIES ASAP system, refer to CMS Web site 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 calculation of the quality measure would be based on the data collection of standardized items to be included in the MDS. The function items used to calculate this measure are the same set of functional status data items that have been added to the IRF-PAI version 1.4, for the purpose of providing standardized resident assessment data elements under the domain of functional status, which is required by the IMPACT Act.

If finalized for implementation into the SNF QRP, the MDS would be modified so as to enable us to calculate this quality measure using additional data elements that are standardized with the IRF-PAI and such data would be obtained at the time of admission and discharge for all SNF residents covered under a Part A stay. The standardized items used to calculate this proposed quality measure do not duplicate existing Section G items currently used for data collection within the MDS. The quality measure and standardized data element specifications for the Application of IRF Functional Outcome Measure: Change in Self-Care Score for Medical Rehabilitation Patients (NQF #2633) can be found on the SNF QRP Measures and Technical Information Web site 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.*

(b) Application of IRF Functional Outcome Measure: Change in Mobility Score for Medical Rehabilitation Patients (NQF #2634)

This quality measure is an application of the outcome measure finalized in the IRF QRP entitled, IRF Functional Outcome Measure: Change in Mobility Score for Medical Rehabilitation Patients (NQF #2634). This quality measure estimates the risk-adjusted mean improvement in mobility score between admission and discharge among SNF residents. A summary of this quality measure can be accessed on the NQF Web site: *http://www.qualityforum.org/qps/2634.* Detailed specifications for this quality measure can be accessed at *http://www.qualityforum.org/ProjectTemplateDownload.aspx?SubmissionID=2634.*

As previously noted, residents seeking care in SNFs include those whose illness, injury, or condition has resulted in a loss of function, and for whom rehabilitative care is expected to help regain that function. Several studies found patients' functional outcomes vary based on treatment. Physical and occupational therapy treatment was associated with greater functional gains, shorter stays, and a greater likelihood of a discharge to a community. Among SNF residents receiving rehabilitation services, the amount of therapy prescribed can vary widely, and this variation is not always associated with resident characteristics. This variation in rehabilitation services supports the need to monitor SNF resident's functional outcomes, as we believe there is an opportunity for improvement in this area.

The functional outcome measure, the Application of IRF Functional Outcome Measure: Change in Mobility Score for Medical Rehabilitation Patients (NQF #2634), requires the collection of admission and discharge functional status data by trained clinicians using standardized resident data elements that assess specific functional mobility activities such as toilet transfer and walking. These mobility items are daily activities that clinicians typically assess at the time of admission and/or discharge to determine resident's needs, evaluate resident progress, and prepare residents and families for a transition to home or to another care provider. The standardized mobility function items are coded using a 6-level rating scale that indicates the resident's level of independence with the activity; higher scores indicate more independence.

The functional assessment items included in the outcome quality measures were originally developed and tested as part of the Post-Acute Care Payment Reform Demonstration version of the CARE Item Set, which was designed to standardize assessment of patients' status across acute and post-acute providers, including SNFs, HHAs, IRFs, and LTCHs.

This outcome quality measure also requires the collection of risk factors data, such as resident functioning prior to the current reason for admission, history of falls, bladder continence, communication ability and cognitive function, at the time of admission.

A cross-setting function TEP convened by our measure development contractor on September 9, 2013 provided input on the initial technical specifications of this proposed quality measure, the Application of IRF Functional Outcome Measure: Change in Mobility Score for Medical Rehabilitation Patients (NQF #2634). The TEP was supportive of the implementation of this measure and supported our efforts to standardize patient/resident assessment data elements. The TEP summary report is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

The list of measures under consideration for the SNF QRP, including this quality measure, was released to the public on November 27, 2015, and early comments were submitted between December 1 and December 7, 2015. The MAP met on December 14 and 15, 2015, sought public comment on this measure from December 23, 2015, to January 13, 2015, and met on January 26 and 27, 2016. The NQF provided the MAP's input to us as required under section 1890A(a)(3) of the Act in the final report, MAP 2016 Considerations for Implementing Measures for Federal Programs: Post-Acute and Long-Term Care, which is available at *http://www.qualityforum.org/Setting_Priorities/Partnership/MAP_Final_Reports.aspx.* The MAP recognized that this measure is an adaptation of currently endorsed measures for the IRF population, and encouraged continued development to ensure alignment across PAC settings. They also noted there should be some caution in the interpretation of measure results due to patient/resident differentiation between facilities. To alignment across PAC settings, the self-care items included in the proposed quality measure are the same self-care items that are included in the IRF-PAI Version 1.4. We agree with the MAP that patient/resident populations can vary across IRFs and SNFs, and we have taken this issue into consideration while selecting and testing the risk adjustors, which include medical conditions, admission function, prior functioning and comorbidities. The risk-adjustors for the IRF and the SNF versions of this measure differ by the inclusion of adjustors such as comorbidities in the IRF measure. As noted, though there are differences between the measures we believe that the differences in risk adjustment will not hinder future comparability across measures.

The MAP also noted possible duplication as the MDS already includes function data elements. The data elements for the measure are similar, but not the same as the existing MDS Section G function data elements. The data elements for the measures include those that are the proposed standardized resident assessment data elements for function. The MAP also stressed the importance of considering burden on providers when measures are considered for implementation. We appreciate the issue of burden and have taken that into consideration in developing the measure. Please refer to the FY 2016 SNF PPS final rule (80 FR 46428) for more information on the MAP.

The MAP's overall recommendation was for ''encourage further development.'' More information about the MAP's recommendations for this proposed measure is available at *http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=81593.*

Since the MAP's review and recommendation for further development, we have continued to develop this measure including soliciting input from a TEP, providing a public comment opportunity, and providing an update on measure development to the MAP via the feedback loop. More specifically, our measure development contractor convened a SNF-specific TEP on May 5, 2016 to provide further input on the technical specifications of this proposed quality measure by reviewing the IRF specifications and the specifications of competing and related function quality measures. Overall, the TEP was supportive of the measure and supported our efforts to standardize patient/resident assessment data elements. The SNF-specific function TEP summary report is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

We also solicited stakeholder feedback on the development of this measure by means of a public comment period open from October 7, until November 4, 2016. There was general support of the measure concept and the importance of functional improvement. Comments on the measure varied, with some commenters supportive of the measure, while others were either not in favor of the measure, or in favor of suggested potential modifications to the measure specifications. The public comment summary report for the proposed 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.*

We also engaged with the NQF convened MAP when we presented an update on the development of this quality measure on October 19, 2016, during a MAP feedback loop meeting. Slides from that meeting are available at *http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id amp;ItemID=83640.*

During the development of this measure, we have monitored and reviewed NQF-endorsed measures that are competing and related. We identified seven competing and related quality measures focused on improvement in mobility for residents in the SNF setting entitled: (1) CARE: Improvement in Mobility (NQF #2612); (2) Functional Change: Change in Mobility Score (NQF 2774); (3) Functional Status Change for Patients with Knee Impairments (NQF #0422); (4) Functional Status Change for Patients with Hip Impairments (NQF #0423); (5) Functional Status Change for Patients with Foot and Ankle Impairments (NQF #0424); (6) Functional Status Change for Patients with Lumbar Impairments (NQF #0425); and (7) Change in Basic Mobility as Measures by the AM–PAC (NQF #0429). We reviewed the technical specifications for these seven measures carefully and compared them with the specifications of the proposed quality measure, the Application of IRF Functional Outcome Measure: Change in Mobility Score for Medical Rehabilitation Patients (NQF #2634) and have noted the following differences in the technical specifications: (1) The number of risk adjustors and variance explained by these risk adjustors in the regression models; (2) the use of functional assessment items that were developed and tested for cross-setting use; (3) the use of items that are already on the MDS 3.0 and what this means for burden; (4) the handling of missing functional status data; and (5) the use of exclusion criteria that are baseline clinical conditions. We describe these key specifications of the proposed outcome measure, the Application of IRF Functional Outcome Measure: Change in Mobility Score for Medical Rehabilitation Patients (NQF #2634), below in more detail.

Our literature review, input from technical expert panels, public comment feedback, and analyses demonstrated the importance of adequate risk adjustment of admission case mix factors for functional outcome measures. Inadequate risk adjustment of admission case mix factors may lead to erroneous conclusions about the quality of care delivered within the facility, and thus is a potential threat to the validity of a quality measure that examines outcomes of care, such as functional status. The quality measure, the Application of IRF Functional Outcome Measure: Change in Mobility Score for Medical Rehabilitation Patients (NQF #2634) risk adjusts for more than 60 risk factors, explaining approximately 23 percent of the variance in change in function, and includes all of the following risk adjusters: Prior functioning, prior device use, age, functional status at admission, primary diagnosis and comorbidities. These are key predictors of functional performance and need to be accounted for in any facility-level functional outcome quality measure.

Another key feature of the proposed measure, Application of IRF Functional Outcome Measure: Change in Mobility Score for Medical Rehabilitation Patients (NQF #2634), is that it uses the functional assessment data elements and the associated rating scale that were developed and tested for cross-setting use. The measure uses functional assessment items from the CARE Item Set, which were developed and tested as part of the PAC PRD between 2006 and 2010.

The items were designed to build on the existing science for functional assessment instruments, and included a review of the strengths and limitations of existing functional assessment instruments. An important strength of the cross-setting function items from the CARE instrument is that they allow tracking of patients' and residents' functional outcomes as they move across post-acute settings. Specifically, the CARE Item Set was designed to standardize assessment of patients' and residents' status across acute and post-acute settings, including SNFs, IRFs, LTCHs, and HHAs. MedPAC has publicly supported a coordinated approach to measurement across settings using standardized resident assessment data elements.

A third important consideration is that some of the data elements associated with the measure, Application of IRF Functional Outcome Measure: Change in Mobility Score for Medical Rehabilitation Patients (NQF #2634), are already included on the MDS in section GG, because we adopted a cross-setting function process measure in the SNF QRP FY 2016 Final Rule (FR 80 46444 through 46453), and seven of the mobility data elements necessary to calculate that quality measure, an Application of the Percent of Long-Term Care Hospital Patient with a Functional Assessment and a Care Plan that Addresses Function (NQF #2631) are used to calculate the proposed quality measure. Provider burden of reporting on multiple measures was a key consideration discussed by stakeholders in our recent TEP: *https://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 believe it is important to include the records of residents with missing functional assessment data when calculating a facility-level functional outcome quality measure for SNFs. The measure, Application of IRF Functional Outcome Measure: Change in Mobility Score for Medical Rehabilitation Patients (NQF #2634), incorporates a method to address missing functional assessment data.

We believe certain clinically-defined exclusion criteria are important to specify in a functional outcome quality measure to maintain the validity of the quality measure. Exclusions for the proposed quality measure, Change in Mobility Score for Medical Rehabilitation Patients (NQF #2634), were selected through a literature review, input from TEPs, and input from the public comment process. The Application of IRF Functional Outcome Measure: Change in Mobility Score for Medical Rehabilitation Patients (NQF #2634) is intended to capture improvement in mobility from admission to discharge for residents who are admitted with an expectation of functional improvement. Therefore, we exclude residents with certain conditions, for example progressive neurologic conditions, because these residents are typically not expected to improve on mobility skills for activities such as walking. Furthermore, we exclude residents who are independent on all mobility items at the time of admission, because no improvement can be measured with the selected set of items by discharge. Inclusion of residents with limited expectation for improvement could introduce incentives for SNF providers to limited access to these residents.

Our measure developer contractor presented and discussed these technical specification differentiations during the May 6, 2016 TEP meeting to obtain TEP input on preferred specifications for valid functional outcome quality measures. The differences in measure specifications and the TEP feedback are presented in the TEP Summary Report, which is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/*

IMPACT-Act-Downloads-and-Videos.html.

Data for the quality measure, the Application of IRF Functional Outcome Measure: Change in Mobility Score for Medical Rehabilitation Patients (NQF #2634), would be collected using the MDS, with the submission through the QIES ASAP system. For more information on SNF QRP reporting through the QIES ASAP system, refer to *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 calculation of the quality measure would be based on the data collection of standardized items to be included in the MDS. The function items used to calculate this measure are the same set of functional status data items that have been added to the IRF–PAI version 1.4, for the purpose of providing standardized resident assessment data elements under the domain of functional status. If this quality measure is finalized for implementation in the SNF QRP, the MDS would be modified so as to enable the calculation of these standardized items that are used to calculate this proposed quality measure. The collection of data by means of the standardized items would be obtained at admission and discharge. The standardized items used to calculate this quality measure do not duplicate existing items currently used for data collection within the MDS. The quality measure and standardized data element specifications for the Application of IRF Functional Outcome Measure: Change in Mobility Score for Medical Rehabilitation Patients (NQF #2634) is available on the SNF QRP Measures and Technical Information Web site 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.*

(c) Application of IRF Functional Outcome Measure: Discharge Self-Care Score for Medical Rehabilitation Patients (NQF #2635)

This quality measure is an application of the outcome quality measure finalized in the IRF QRP entitled, IRF Functional Outcome Measure: Discharge Self-Care Score for Medical Rehabilitation Patients (NQF #2635). The quality measure estimates the percentage of SNF residents who meet or exceed an expected discharge self-care score. A summary of this quality measure can be accessed on the NQF Web site at *http://www.qualityforum.org/qps/2635.* Detailed specifications for the quality measure can be accessed at *http://www.qualityforum.org/ProjectTemplateDownload.aspx?SubmissionID=2635.*

As previously noted, residents seeking care in SNFs include individuals whose illness, injury, or condition has resulted in a loss of function, and for whom rehabilitative care is expected to help regain that function. Several studies found patients' functional outcomes vary based on treatment by physical and occupational therapists. Therapy was associated with greater functional gains, shorter stays, and a greater likelihood of discharge to community. Among SNF residents receiving rehabilitation services, the amount of treatment prescribed can vary widely, and this variation is not associated with resident characteristics. This variation in rehabilitation services supports the need to monitor SNF resident's functional outcomes, as we believe there is an opportunity for improvement in this area.

The outcome quality measure, Application of IRF Functional Outcome Measure: Discharge Self-Care Score or Medical Rehabilitation Patients (NQF #2635), requires the collection of functional status data at admission and discharge by trained clinicians using standardized resident assessment data elements such as eating, oral hygiene, and lower body dressing. These self-care items are daily activities that clinicians typically assess at the time of admission and discharge to determine residents' needs, evaluate resident progress, and prepare residents and families for a transition to home or to another provider. The self-care function data elements are coded using a 6-level rating scale that indicates the resident's level of independence with the activity; higher scores indicate more independence.

The functional assessment items included in the outcome quality measures were originally developed and tested as part of the Post-Acute Care Payment Reform Demonstration version of the CARE Item Set, which was designed to standardize assessment of patients' status across acute and post-acute providers, including SNFs, HHAs, IRFs, and LTCHs.

This outcome quality measure also requires the collection of risk factors data, such as resident functioning prior to the current reason for admission, bladder continence, communication ability, and cognitive function at the time of admission.

A cross-setting function TEP convened by our measure development contractor on September 9, 2013 provided input on the initial technical specifications of this proposed quality measure, the Application of IRF Functional Outcome Measure: Discharge Self-Care Score for Medical Rehabilitation Patients (NQF #2635). The TEP was supportive of the implementation of this measure and supported CMS's efforts to standardize patient/resident assessment data elements. The TEP summary report is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

The MAP met on December 14 and 15, 2015, and provided input on the proposed measure, Application of IRF Functional Outcome Measure: Discharge Self-Care Score for Medical Rehabilitation Patients (NQF #2635) for use in the SNF QRP. The MAP recognized that this quality measure is an adaptation of a currently endorsed measure for the IRF population, and encouraged continued development to ensure alignment of this measure across PAC settings. The MAP also noted there should be some caution in the interpretation of measure results due to patient/resident differentiation between facilities. The MAP also stressed the importance of considering burden on providers when measures are considered for implementation. The MAP also noted possible duplication as the MDS already includes function data elements. The data elements for the proposed measure are similar, but not the same as the existing MDS function data elements. The data elements for the measures include those that are the proposed standardized assessment data elements for function. The MAP's overall recommendation was to ''encourage further development.'' More information about the MAP's recommendations for this measure is available at *http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=81593.*

Since the 2015 MAP's review and recommendation for further development, we have continued to develop this measure including soliciting input via a TEP, proving a public comment opportunity and providing an update on measure development to the MAP via the feedback loop. More specifically, our measure development contractor convened a SNF-specific TEP on May 5, 2016 to provide further input on the

technical specifications of this quality measure by reviewing the IRF specifications and the specifications of competing and related function quality measures. Overall, the TEP was supportive of the measure. Specifically, they supported the risk adjustors, suggested some additional risk adjustors, supported the exclusion criteria and supported CMS's efforts to standardize patient/resident assessment data elements. The SNF-specific function TEP summary report is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

We also solicited stakeholder feedback on the development of this measure by means of a public comment period open from October 7, 2016 until November 4, 2016. There was general support of the measure concept and the importance of functional improvement. Comments on the measure varied, with some commenters supportive of the measure, while others were either not in favor of the measure, or in favor of suggested potential modifications to the measure specifications. Some comments focused on suggestions for additional risk adjustors, and the data elements. 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.*

We also engaged with stakeholders when we presented an update on the development of this quality measure to the MAP on October 19, 2016, during a MAP feedback loop meeting. Slides from that meeting are available at *http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=83640.*

During the development of this measure, we monitored and reviewed NQF-endorsed measures that are competing and related. We identified six competing and related quality measures focused on self-care functional improvement for residents in the SNF setting entitled: (1) CARE: Improvement in Self Care (NQF #2613); (2) Functional Change: Change in Self-Care Score (NQF #2286); (3) Functional Status Change for Patients with Shoulder Impairments (NQF #0426); (4) Functional Status Change for Patients with Elbow, Wrist and Hand Impairments (NQF #0427); (5) Functional Status Change for Patients with General Orthopedic Impairments (NQF #0428); and (6) Change in Daily Activity Function as Measures by the AM–PAC (NQF #0430).

As described above, we reviewed the technical specifications for these six measures and compared them with the specifications for the quality measure, Application of IRF Functional Outcome Measure: Discharge Self-Care Score for Medical Rehabilitation Patients (NQF #2635) and, as described in detail above, we noted the following differences in the technical specifications: (1) The number of risk adjustors and variance explained by these risk adjustors in the regression models; (2) the use of functional assessment items that were developed and tested for cross-setting use; (3) the use of items that are already on the MDS 3.0 and what this means for burden; (4) the handling of missing functional status data; and (5) the use of exclusion criteria that are baseline clinical conditions.

Consistent with the other functional outcome measures, the specifications for this quality measure, Application of IRF Functional Outcome Measure: Discharge Self-Care Score for Medical Rehabilitation Patients (NQF #2635), were developed based on our literature review, input from technical expert panels, public comment feedback and data analyses. The details about the specifications for the measures described above also apply to this quality measure. Overall, the TEP supported the use of a risk adjustment model that addressed prior functioning, admission functioning, prior diagnosis and comorbidities. In addition, they supported exclusion criteria that would address functional improvement expectations of residents.

Our measure developer contractor presented and discussed these technical specification differentiations during the May 6, 2016 TEP meeting to obtain TEP input on preferred specifications for valid functional outcome quality measures. The differences in measure specifications and the TEP feedback are presented in the TEP Summary Report, which is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

Data for the quality measure, the Application of IRF Functional Outcome Measure: Discharge Self-Care Score for Medical Rehabilitation Patients (NQF #2635), would be collected using the MDS, with the submission through the QIES ASAP system. For more information on SNF QRP reporting through the QIES ASAP system, refer to CMS Web site 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 calculation of the proposed quality measure would be based on the data collection of standardized items to be included in the MDS. The function items used to calculate this measure are the same set of functional status data items that have been added to the IRF–PAI version 1.4, for the purpose of providing standardized resident assessment data elements under the domain of functional status.

The collection of data by means of the standardized items would be obtained at admission and discharge. The standardized items used to calculate this quality measure do not duplicate existing items currently used for data collection within the MDS. The quality measure and standardized data element specifications for the Application of IRF Functional Outcome Measure: Discharge Self-Care Score for Medical Rehabilitation Patients (NQF #2635) can be found on the SNF QRP Measures and Technical Information Web site 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.*

If finalized for implementation into the SNF QRP, the MDS would be modified so as to enable us to calculate the proposed measure using additional data elements that are standardized with the IRF–PAI and such data would be obtained at the time of admission and discharge for all SNF residents covered under a Part A stay.

(d) Application of IRF Functional Outcome Measure: Discharge Mobility Score for Medical Rehabilitation Patients (NQF #2636)

This quality measure is an application of the outcome quality measure finalized in the IRF QRP entitled, IRF Functional Outcome Measure: Discharge Mobility Score for Medical Rehabilitation Patients (NQF #2636). This quality measure estimates the percentage of SNF residents who meet or exceed an expected discharge mobility score. A summary of this quality measure can be accessed on the NQF Web site: *http://www.qualityforum.org/qps/2636.* Detailed specifications for this quality measure can be accessed at *http://www.qualityforum.org/ProjectTemplateDownload.aspx?SubmissionID=2636.*

As previously noted, residents seeking care in SNFs include individuals whose illness, injury, or condition has resulted in a loss of function, and for whom rehabilitative care is expected to help regain that function. Several studies found patients' functional outcomes vary based on treatment by physical and occupational therapists. Therapy was associated with greater functional gains, shorter stays, and a greater likelihood of discharge to community. Among SNF residents receiving rehabilitation services, the amount of treatment prescribed can vary widely, and this variation is not associated with resident characteristics. This variation in rehabilitation services supports the need to monitor SNF resident's functional outcomes, as we believe there is an opportunity for improvement in this area.

The functional outcome measure, Application of IRF Functional Outcome Measure: Discharge Mobility Score for Medical Rehabilitation Patients (NQF #2636), requires the collection of admission and discharge functional status data by trained clinicians using standardized resident data elements that assess specific functional mobility activities such as bed mobility and walking. These standardized mobility items are daily activities that clinicians typically assess at the time of admission and/or discharge to determine residents' needs, evaluate resident progress and prepare residents and families for a transition to home or to another care provider. The standardized mobility function items are coded using a 6-level rating scale that indicates the resident's level of independence with the activity; higher scores indicate more independence.

The functional assessment items included in the outcome quality measures were originally developed and tested as part of the Post-Acute Care Payment Reform Demonstration version of the CARE Item Set, which was designed to standardize assessment of patient or resident status across acute and post-acute providers, including SNFs, HHAs, IRFs, and LTCHs.

This quality measure requires the collection of risk factors data, such as resident functioning prior to the current reason for admission, history of falls, bladder continence, communication ability and cognitive function, at the time of admission.

A cross-setting function TEP convened by our measure development contractor on September 9, 2013 provided input on the initial technical specifications of this quality measure, Application of IRF Functional Outcome Measure: Discharge Mobility Score for Medical Rehabilitation Patients (NQF #2636). The TEP was supportive of the implementation of this measure and supported our efforts to standardize patient assessment data elements. The TEP summary report is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

The MAP met on December 14 and 15, 2015, and provided input on the measure, Application of IRF Functional Outcome Measure: Discharge Mobility Score for Medical Rehabilitation Patients (NQF #2636), for use in the SNF QRP. The MAP recognized that this quality measure is an adaptation of a currently endorsed measure for the IRF population, and encouraged continued development to ensure alignment of this measure across PAC settings. The MAP noted there should be some caution in the interpretation of measure results due to patient/resident differentiation between facilities. The MAP also stressed the importance of considering burden on providers when measures are considered for implementation. The MAP also noted possible duplication as the MDS already includes function data elements. The data elements for the proposed measure are similar, but not the same as the existing MDS function data elements. The data elements for the measure include those that are the standardized patient data elements for function. The MAP's overall recommendation was to ''encourage further development.'' More information about the MAP's recommendations for this proposed measure is available at *http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=81593.*

Since the MAP's review and recommendation for further development, we have continued to develop this measure including soliciting input via a TEP, proving a public comment opportunity and providing an update on measure development to the MAP via the feedback loop. More specifically, our measure development contractor convened a SNF-specific TEP on May 5, 2016, to provide further input on the technical specifications of this quality measure by reviewing the IRF specifications and the specifications of competing and related function quality measures. Overall, the TEP was supportive of the measure and supported our efforts to standardize patient/resident assessment data elements. The SNF-specific function TEP summary report is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

We also solicited stakeholder feedback on the development of this measure by means of a public comment period open from October 7, 2016, until November 4, 2016. There was general support of the measure concept and the importance of functional improvement. Comments on the measure varied, with some commenters supportive of the measure, while others were either not in favor of the measure, or suggested potential modifications to the measure specifications.

The public comment summary report for the proposed 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.*

We also engaged with stakeholders when we presented an update on the development of this quality measure to the MAP on October 19, 2016, during a MAP feedback loop meeting. Slides from that meeting are available at *http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=83640.*

During the development of this measure, we have monitored and reviewed the NQF-endorsed measures that are competing and related. We identified seven competing and related quality measures focused on mobility functional improvement for residents in the SNF setting entitled: (1) CARE: Improvement in Mobility (NQF #2612); (2) Functional Change: Change in Mobility Score (NQF #2774); (3) Functional Status Change for Patients with Knee Impairments (NQF #0422); (4) Functional Status Change for Patients with Hip Impairments (NQF #0423); (5) Functional Status Change for Patients with Foot and Ankle Impairments (NQF #0424); (6) Functional Status Change for Patients with Lumbar Impairments (NQF #0425); and (7) Change in Basic Mobility as Measures by the AM–PAC (NQF #0429). As described above, we reviewed the technical specifications for these seven measures carefully and compared them with the specifications of the proposed quality measure, Application of IRF Functional Outcome Measure: Discharge Mobility Score for Medical Rehabilitation Patients (NQF #2636) and have noted the following differences in the technical specifications: (1) The

number of risk adjustors and variance explained by these risk adjustors in the regression models; (2) the use of functional assessment items that were developed and tested for cross-setting use; (3) the use of items that are already on the MDS 3.0 and what this means for burden; (4) the handling of missing functional status data; and (5) the use of exclusion criteria that are baseline clinical conditions.

Consistent with the other functional outcome measures, the specifications for this quality measure, Application of IRF Functional Outcome Measure: Discharge Mobility Score for Medical Rehabilitation Patients (NQF #2636), were developed based on our literature review, input from technical expert panels, public comment feedback and data analyses. The details about how the specifications for the measures differ as described in the previous functional outcome measure sections, also apply to this quality measure.

Our measure developer contractor presented and discussed these technical specification differentiations during the May 6, 2016 TEP meeting to obtain TEP input on preferred specifications for valid functional outcome quality measures. The differences in measure specifications and the TEP feedback are presented in the TEP Summary Report, which is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

Data for the quality measure, the Application of IRF Functional Outcome Measure: Discharge Mobility Score for Medical Rehabilitation Patients (NQF #2636), would be collected using the MDS, with the submission through the QIES ASAP system. Additional information on SNF QRP reporting through the QIES ASAP system can be found on the CMS Web site 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 calculation of the quality measure would be based on the data collection of standardized items to be included in the MDS. The function items used to calculate this measure are the same set of functional status data items that have been added to the IRF-PAI version 1.4, for the purpose of providing standardized resident assessment data elements under the domain of functional status.

The collection of data by means of the standardized items would be obtained at admission and discharge. The standardized items used to calculate this quality measure do not duplicate existing items currently used for data collection within the MDS. The quality measure and standardized resident data element specifications for the Application of IRF Functional Outcome Measure: Discharge Change in Mobility Score for Medical Rehabilitation Patients (NQF #2636) can be found on the SNF QRP Measures and Technical Information Web site 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.*

If finalized for implementation into the SNF QRP, the MDS would be modified so as to enable us to calculate the measure using additional data elements that are standardized with the IRF-PAI and such data would be obtained at the time of admission and discharge for all SNF residents covered under a Part A stay.

We sought public comments on our proposal to adopt the four functional outcome quality measures, entitled Application of IRF Functional Outcome Measure: Change in Self-Care Score for Medical Rehabilitation Patients (NQF #2633); Application of IRF Functional Outcome Measure: Change in Mobility Score for Medical Rehabilitation Patients (NQF #2634);, Application of IRF Functional Outcome Measure: Discharge Self-Care Score for Medical Rehabilitation Patients (NQF #2635); and Application of IRF Functional Outcome Measure: Discharge Mobility Score for Medical Rehabilitation Patients (NQF #2636), beginning with the FY 2020 SNF QRP. All of the comments we received addressed all four measures, and our discussion of them follows.

Comment: Several stakeholders supported the adoption of all four functional status quality measures into the SNF QRP. One commenter noted that self-care and mobility are of particular concern for persons with advanced illness. This commenter further noted that function affects daily life and quality of life for both persons and caregivers, and that tracking this information during a SNF stay and at discharge would improve transitions. The commenter encouraged us to increase measurement of functional status for all patients in all settings. Another commenter who supported the measures noted that valid and reliable measures of functional outcomes are important for informing treatment planning. Two commenters supported all 4 functional status quality measures in the SNF setting, and noted their general support for quality measures in all PAC settings that assess functional status and the real-life needs of beneficiaries. These two commenters believe that these four functional outcome measures move the SNF QRP in this direction. Another commenter stated that having a core set of data elements will allow for tracking of function across the continuum of care and is in alignment with the goals of the IMPACT Act. Another commenter supported our efforts to improve quality of care and ensure appropriate resource allocation among PAC settings, and specifically voiced agreement for adapting the NQF-endorsed functional outcome measures from the IRF setting to the SNF setting to align measures noting the intent of the IMPACT Act. This commenter stated that measures should be clinically relevant, representative for a given setting and patient population, and meaningful to patients and families.

Response: We appreciate the commenters' support for the four functional status outcome quality measures that we proposed to adopt for the SNF QRP. We agree that patient and resident functioning in the areas of self-care care and mobility are clinically relevant and are an important area of quality in post-acute care (PAC) settings. In addition, we believe that examining resident functioning during the SNF stay will help SNFs focus on optimizing residents' functioning and discharge planning and support residents' transitions from the SNF to home or another setting. Finally, we agree that valid and reliable measures of functional outcomes will assist SNFs in planning treatment aimed at increasing or maintaining functional status.

Comment: One commenter offered support for these measures in concept, but expressed concern that the proposed measures have not been tested in the SNF setting. The commenter recommended that testing across population types take place prior to any public reporting to avoid confusion among providers and consumers.

Response: CMS strongly agrees that item and quality measure validity and reliability are important. The self-care and mobility items underwent several types of testing across post-acute care settings, including SNFs, as part of the Post-Acute Care Payment Reform Demonstration (PAC PRD). This testing, which included data from 60 SNFs (contributing almost 4,000 CARE

assessments) examined the items' feasibility, reliability, and validity. Overall, these results indicate moderate to substantial agreement on these items. Details regarding the reliability and validity testing, can be found in reports entitled *The Development and Testing of the Continuity Assessment Record and Evaluation (CARE) Item Set, Volumes 1 through 3, Continuity Assessment Record and Evaluation (CARE) Item Set: Video Reliability Testing,* and *Continuity Assessment Record and Evaluation (CARE) Item Set: Additional provider-Type Specific Interater Reliability Analyses.* These reports are available at *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/CARE-Item-Set-and-B-CARE.html.*

As part of our quality measure development work, we conducted additional reliability and validity testing, including Rasch analysis, which showed acceptable reliability and validity, and these results were discussed during the May 2016 TEP meeting and are summarized in the SNF Function TEP Summary Report, which is 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.* Therefore, given the overall findings of these reliability and validity analyses, we believe that the proposed functional outcome measures are sufficiently reliable for the SNF QRP.

In addition, beginning October 1, 2016, SNFs are reporting several of the self-care and mobility data elements that are needed to calculate these measures. The quality measure, an Application of the Percent of LTCH Patients with a Functional Assessment and a Care Plan that Addresses Function (NQF #2631), was finalized for use in the SNF QRP in FY 2016 (80 FR 46444 through 46453). This process measure includes several of the self-care and mobility items included in the SNF functional outcome measures, and we are conducting tests of the reliability and validity of that data. We conduct ongoing analysis of reliability and validity of adopted measures.

Comment: One commenter did not support the proposed function measures because the NQF has not endorsed them for the SNF setting and the Measure Applications Partnership (MAP) recommended continued development. Two commenters recommended that we seek rapid NQF endorsement for the four outcome measures to remove the ''application of'' and ''IRF'' wording from the measure titles and to prevent confusion among consumers, policymakers, and payers when displayed. One of these commenters stated that quality performance outcomes reported by an NQF endorsed measure in one setting may not necessarily be comparable to an ''application'' of the same measure in another setting due to differences in patient populations, payment policy, and specific measure calculation details, case mix adjustors such as co-morbidities, and other measure details. Another commenter recommended that the official name of the proposed measure distinguish them as SNF quality measures, which would decrease the public confusion when viewing them on Nursing Home Compare.

Response: While these measures are not currently NQF-endorsed for SNFs, we recognize that the NQF endorsement process is an important part of measure development and plan to submit these four measures for consideration of NQF endorsement after one full year of data collection. We initially presented the four SNF outcome measures to the MAP in December 2015. After the MAP meeting, we continued development as recommended. Our measure developer contractor convened a SNF Function TEP in May 2016 and we then requested and received public comment via the CMS Measures Management Web site. In October 2016, we presented a review of our additional measure development work to the MAP as part of the feedback loop to give an update on the measure development activities.

We appreciate the comments pertaining to NQF endorsement of the measures before they are publicly displayed and comments on the titling of the proposed functional outcome measures. With regard to the measure title, we recognize the confusion of leveraging the words ''IRF'' in our title application when we are collecting for a SNF population, and we will reassess the titling for these outcome measures to decrease confusion among all stakeholders.

Comment: Several commenters expressed concern about the added burden of collecting data for the functional outcome measures. One commenter noted that the addition of the section GG items needed for the function outcome measures will increase the time providers need to complete residents' assessments. A few commenters stated that changes in the MDS as a result of these measures will involve additional staff time and resources for training and monitoring compliance. One commenter suggested that we provide financial support for the additional reporting burden.

Response: We appreciate the commenters' concerns associated with the proposed functional outcome measures. We recognize that any new data collection is associated with burden and take such concerns under consideration when developing and selecting quality measures. As we develop quality measures, we review existing items and consider the appropriateness of adding or deleting any items. We note that some of the data elements associated with the measure are already included on the MDS in section GG, because we adopted a cross-setting function process measure in the SNF QRP FY 2016 Final Rule (80 FR 46444 through 46453). Three of the self-care data elements and seven mobility data elements necessary to calculate that quality measure, an Application of the Percent of Long-Term Care Hospital Patient with a Functional Assessment and a Care Plan that Addresses Function (NQF #2631) are used to calculate the quality measure and are finalized in this rule as standardized resident assessment data elements.

Comment: Three commenters noted that the requirement to assess residents while utilizing both the section G—Functional Status and section GG—Functional Abilities and Goals items on the MDS is burdensome. One of the commenters explained that to address the same functional activities in two different sections of the MDS, with different item definitions, and with different look-back periods, is excessively burdensome, and introduces unnecessary risk for reporting errors. The two other commenters further suggested that we analyze the section G mobility and self-care items that address the same or similar domains in section GG to identify opportunities to eliminate the redundant and non-compliant mobility and self-care items from section G.

Response: We recognize that the items in section G and section GG address similar domains of mobility and self-care. However, for the SNF QRP, we believe that the section GG items and the associated 6-level scale will allow us to better distinguish change at the highest and lowest levels of functioning by documenting minimal change from no change at the low end of the scale. This is important for measuring progress in some of the most complex cases treated in PAC. The items in section GG were developed with input from the clinical therapy communities to better measure the change in function,

regardless of the severity of the individual's functional limitations. To reduce the potential burden associated with collecting additional items, we have included several mechanisms in the section GG to reduce the number of items that apply to any one resident. First, in section GG, there are skip patterns pertaining to walking and wheelchair mobility that allow the clinician to skip items if the resident does not walk or does not use a wheelchair, respectively. The skip patterns mean that only a subset of section GG items are needed for most residents. Second, section GG items will only be collected at admission and discharge.

Comment: Two comments requested more detailed information about how the functional outcome measures could be used to improve quality and how we expect to use the information.

Response: We believe that examining residents' functional outcomes will help SNF staff focus on optimizing patients' functioning and supporting patients' transition from the SNF to home or another setting. Furthermore, we believe that the feedback we provide to SNFs on these measures will allow providers to monitor their performance on key rehabilitation outcomes, relative to other facilities, and identify opportunities to improve their quality of care.

Comment: One commenter voiced concern about the proposal to include functional outcome measures that focus on functional improvement without also proposing measures that cover SNF residents who are in the facility for functional maintenance or the prevention or slowing of functional decline. The commenter stated that the standards of care and goals for patients in an IRF cannot be adopted for SNFs unless an additional measure that focuses on residents covered under functional maintenance is also adopted. The commenter further noted that adoption of the four functional outcome measures will send the wrong message to SNFs and indicate they are being judged solely on whether they improve residents' functioning. The commenter recommends delaying implementation of these measures until a maintenance measure can also be implemented simultaneously. This commenter disagreed that the exclusion of patients not receiving physical therapy or occupational therapy is an appropriate proxy for SNF residents for whom there is no expectation of functional improvement and suggested we consider another measure that does not penalize SNFs that provide maintenance therapy.

Response: We agree that our measures should address maintenance and the prevention or slowing of functional decline, and we note that the functional process measure, Application of Percent of LTCH Patients with an Admission and Discharge Functional Assessment and a Care Plan that Addresses Function (NQF #2631), which is already included in the SNF QRP measure set, addresses this topic. The functional process measure requires that a SNF conduct a functional assessment at both admission and discharge and that such assessment include at least one goal related to function. Such functional status goals may focus on maintenance of function, slowing decline in function or functional improvement. Likewise, the proposed discharge functional outcome measures, Application of the IRF Function Outcome Measure: Discharge Self-Care Score for Medical Rehabilitation Patients (NQF #2635) and Application of the IRF Function Outcome Measure: Discharge Mobility Score for Medical Rehabilitation Patients (NQF #2636), calculate the residents' observed and expected discharge functional status. Maintenance of function or slowed decline in function may be expected based on the resident's characteristics and this would be captured in these measures. We also support future quality measurement work that will assess the development of other measures that focus on maintaining function and the slowing of functional decline.

Finally, we would like to note that the Nursing Home Quality Initiative includes two quality measures focused on functional maintenance and slowing decline. These measures are reported to the public on the Nursing Home Compare Web site and are calculated using MDS Section G data elements. We intend to develop similar quality measures focused on maintenance of function and decline in function that would be calculated using section GG Self-Care and Mobility data elements. With regard to unintended consequences, we will monitor potential unintended consequences of this exclusion criterion, and take these suggestions into consideration during our ongoing efforts to improve our quality measures.

Comment: One commenter agreed with the exclusion of residents who do not have an expectation of functional improvement for the 2 change functional outcome measures (Application of IRF Functional Outcome Measure: Change in Self-Care for Medical Rehabilitation Patients (NQF #2633) and Application of IRF Functional Outcome Measure: Change in Mobility Score for Medical Rehabilitation Patients (NQF #2634)) and requested clarification as to how we would identify these residents. The commenter requested additional detail regarding residents who qualify for this exclusion at admission and for residents whose status changes during the SNF stay. The commenter noted that to ensure accurate and appropriate identification of beneficiaries who qualify for this exclusion, CMS needs to provide more detail regarding it. One commenter stated that we should provide additional information regarding how SNFs will be held accountable if the goal changes from expecting functional improvement in a resident to not expecting functional improvement during the resident's stay. Another commenter also voiced concern that changes in residents' goals between admission and discharge are common and would impact outcomes.

Response: For this exclusion criterion, we provide the list of medical conditions that we will use in the Final Rule Specifications for SNF QRP Quality Measures document, which is 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 recognize that a resident's status or goals may change during the SNF stay, and the measures include several exclusions that are applied based on the resident's status at discharge to reflect this change prior to the end of the stay. For example, a resident may experience an incomplete stay due to an urgent medical condition and is discharged to an acute care hospital. We recognize that it is challenging to collect discharge functional assessment data under these circumstances. For this reason, these residents are excluded from the four functional outcome measures. We would also like to clarify that the collection of a patient's goal is simply to track whether a patient's goal was established on admission rather than to track the expectation of function improvement.

Another exclusion criterion in the 4 functional outcome measures relates to residents who are discharged to hospice. This may be a circumstance where a resident's status changed during the stay due to a new medical diagnosis or an unexpected worsening of a resident's condition. The list of all measure exclusions and the specifications for each of these exclusion criteria are

provided in the Final Rule Specifications for SNF QRP Quality Measures document. We will continue to monitor for other examples as part of our ongoing quality measure development work.

Comment: Several commenters disagreed with one proposed exclusion criteria, Residents who do not receive physical or occupational therapy services. Two commenters suggested that we adopt more person-centered criteria that reflect functional improvement expectations in addition to or to replace the current proposed exclusion that focuses on therapy services. The two commenters stated that providers who administer therapy services to residents to maintain, but not improve function, would have lower functional improvement scores and the criterion ''creates a significant disincentive to provide any physical therapy (PT) or occupational therapy (OT) to SNF residents that require skilled services to maintain or delay decline in function.'' One of the two commenters stated this may be a disincentive to provide therapy to residents who fit into the Jimmo class of beneficiaries who may not improve but still need SNF services. One of these commenters recommended that CMS exclude residents whose aggregate ''Admission Performance'' mobility (GG01701) or self-care (GG01301) score (see Step 1 of the CMS proposed quality measures algorithms) is greater than or equal to their ''Discharge Goal'' mobility (GG01702) or self-care (GG01302) score. Another commenter opposed excluding from the functional outcome measures residents who do not receive occupational therapy or physical therapy.

One commenter who disagreed with the proposed exclusions criterion further noted that the exclusion of ''residents who do not receive physical or occupational therapy services,'' for the 4 functional outcome measures is substantively different than the May 2016 SNF Function TEP discussion, and the 2016 CMS Measurement Management Public Comment document. This commenter recognized that the exclusion did refer to ''Residents who do not have an expectation of functional improvement,'' which was subsequently clarified to exclude ''Residents who do not receive physical or occupational therapy services.'' The commentator expressed that no explanation or data analysis was provided to justify the change in the exclusion definition.

Response: We thank the commenters for their feedback and suggestions. We acknowledge the commenters' concern about excluding residents who do not receive physical or occupational therapy services. As noted in the SNF Function TEP Report, our measure development contractor did solicit suggestions from TEP members about methods to operationalize exclusion criteria so that the quality measure would include only residents who were expected to improve functional status, and TEP members did not offer a specific recommendation to address this issue. For residents who are expected to improve their functional abilities, physical and/or occupational therapy would be part of the resident's care plan to assist the resident to relearn how to perform the activity or to learn a new way to perform the activity. With regard to the commenter's suggestion to exclude residents whose aggregate ''Admission Performance'' is greater than or equal to their ''Discharge Goal,'' we would like to clarify that the Function Process Measure requires SNFs to code at least one Discharge Goal item on the 5-day admission assessment. The suggestion would require SNFs to code all function Discharge Goal items, which is not currently required, and this would incur a significant burden on SNFs.

Comment: MedPAC noted the importance of monitoring the accuracy of data that is reported on measures that assess functional status.

Response: We agree with MedPAC on the importance of monitoring the accuracy of functional status data that is reported to CMS, as data accuracy is necessary to calculate reliable and valid quality measures. To that end, we conduct ongoing analyses of the assessment data submitted from PAC providers to ensure accuracy by examining the reliability and validity of the data elements on a quarterly basis.

Comment: One commenter cautioned that the education level and professional expertise of personnel collecting SNF functional outcome measure data are important to consider when analyzing and drawing conclusions about the data.

Response: We recognize that each SNF may have unique workflow issues, which may mean that data collection protocols are not exactly alike. However, we require that SNFs submit accurate data, and we provide training and other resources.

Comment: One commenter supported the general numerator and denominator definitions proposed for the four proposed SNF functional outcome measures.

Response: We appreciate the commenter's support.

Comment: One commenter expressed support for the denominator exclusion criteria proposed for the four proposed SNF functional outcome measures.

Response: We appreciate the commenter's support.

Comment: One commenter expressed concern regarding the exclusion, ''residents who are scored as independent upon admission,'' from the change in self-care score measure and the inclusion of these residents in the self-care discharge score measure. The commenter explained that this will cause confusion among providers, and recommended that further education be offered to providers.

Response: This exclusion criterion only applies to the two change quality measures (Application of IRF Functional Outcome Measure: Change in Self-Care for Medical Rehabilitation Patients (NQF #2633) and Application of IRF Functional Outcome Measure: Change in Mobility Score for Medical Rehabilitation Patients (NQF #2634)), and is related to a measurement issue. A resident who is independent with each of the self-care or mobility activities in section GG at the time of admission would be coded a 6 on each of those items, and any improvement in self-care or mobility skills the resident achieved during the stay could not be measured with the same set of function data elements and rating scale at discharge. Therefore, residents who are at the ''ceiling'' of the self-care or mobility scale at the start of a SNF stay are excluded from the respective change in self-care or change in mobility quality measure. Including these residents in a change quality measure may disadvantage providers serving these residents, as the change in self-care or mobility could not be mathematically higher than zero. We would like to note that residents who are independent with all self-care or mobility activities are included in the discharge self-care and the discharge mobility quality measures, and for the discharge quality measures, maintaining independence with all the self-care or mobility activities is the expected outcome. With regard to provider knowledge about this topic, we recognize the importance of comprehensive training and we intend to provide such training.

Comment: Two commenters noted that the calculation of the 4 functional outcome quality measures requires recoding of ''activity did not occur'' codes. These commenters expressed concern about recoding the ''activity did not occur'' codes (that is, codes 07, 09, 88) to 01—Dependent, and one of the two commenters did not support recoding of missing data as the method was not clear. [The other commenter expressed concern that recoding the

activity not attempted codes to 01 will not accurately reflect resident status or change, and that mobility and self-care tasks being refused, not applicable, or not attempted due to medical or safety concerns, does not necessarily mean the resident is dependent.

Another commenter noted that this recoding can result in different statistical and clinical inferences compared to not recoding items to 01. The commenter recommended further detail regarding the use of ''activity did not occur'' codes and that an analysis be conducted that compares the recoding method to excluding any or all the four ''activity did not occur'' item responses, and provide the percentage of patient stays impacted. The commenter requested that these results be shared with stakeholders for comment before adopting these four proposed functional outcomes measures.

Response: We appreciate the concerns presented by commenters about handling missing data and the ''activity not attempted'' codes. ''Activity did not occur'' codes and missing data are recoded to 01. Dependent to calculate the quality measure. The rationale for this recoding relates to the likelihood that when a resident cannot attempt an activity due to a medical condition or safety concern, that the resident often would have required significant assistance from one or more helpers to complete the activity had the activity been attempted. Thus, the resident would have been considered dependent with the activity. Likewise, the code 09, ''Not applicable,'' is used to indicate that the activity was not attempted, and that the resident did not perform the activity prior to the current illness, injury or exacerbation. We believe our re-coding approach is better than excluding any resident stays that include one or more items coded as ''activity not attempted,'' because excluding these residents would exclude residents who, in general, are lower functioning. That said, we are exploring other methods of recoding items when an activity was not attempted. We believe it is important to continue to monitor the reliability and validity of the functional outcome measures, including issues such as this one. Ongoing analyses of these items and outcomes may provide support for an alternative approach to item recoding in the future.

Comment: One commenter conditionally supported the inclusion of only Medicare Part A residents, but requested that we consider revising this criterion in the future to include SNF Medicare Advantage enrollees. The commenter noted that with growing enrollment in the Medicare Advantage program, excluding these beneficiaries may result in the outcome measure not adequately representing quality of care for the entire SNF. The commenter recommended that we pursue the regulatory and/or statutory approaches necessary to make data reporting and analysis possible include the Medicare Advantage population, and that this was essential so that functional outcomes of all Medicare beneficiaries (Part A or Medicare Advantage) reported by these proposed measures would more accurately represent the quality of care provided by a SNF. Two commenters commented that the description of the proposed measures should specify that the measure estimates outcomes for the Medicare Part A coverage benefit, as opposed to the admission and discharge from a nursing home. The commenter noted this was important because a Medicare Part A resident may remain in the nursing facility at the end of the Part A coverage period, so while the resident may be ''discharged'' from Part A benefits, he/she is not ''discharged'' from the nursing home.

Response: The commenter is correct that the functional outcome measures apply only to Medicare Part A SNF residents. The assessment data for the functional outcome measures would be collected at the start of the SNF Part A stay and the end of the Part A stay. We appreciate the suggestion to expand the proposed measure collection to a Medicare Advantage population. We will take the recommendation to expand the measure population into consideration in future measure development efforts. Additional discussion of the expansion of quality measures to include all residents regardless of payer status can be found in section III.D.2.k.5

Comment: One commenter noted there are meaningful SES, clinical, or other differences between traditional Medicare versus Medicare Advantage (MA) enrollees that could affect comparisons between facilities with different proportion of Medicare Advantage and Part A stays. The commenter further requested that this possibility should be investigated.

Response: For a discussion of social risk factors in the SNF QRP, please see the discussion in section III.D.2.b.1 of this rule.

Comment: One commenter stated that the calculation of the four proposed measures is complex, particularly with respect to the calculation of the expected discharge functional status score using a formula, which may result in providers not understanding the precise target outcome. The commenter further noted that the measure scores might be inappropriately compared across PAC settings even though they are calculated differently using different risk adjustor coefficients. The commenter stated that significant education and ongoing feedback for providers will be necessary when these measures are implemented to improve quality of care and suggested that we simplify the calculations for the functional outcome measures.

Another commenter voiced concern that the calculated ''Expected score'' for the function outcome measures would be an inaccurate point of comparison if the risk adjustors were not accurate. The commenter suggested that we fully evaluate the risk adjustors in a large data sample to ensure they are appropriate prior to implementation. The commenter also suggested that we should have a transparent process that is clearly communicated with stakeholders to clarify and refine risk adjustors for the functional outcome measures. The commenter noted that if there is not a refinement period of the risk adjustors, providers will be penalized for their performance on these measures at the same time that we are examining the risk adjustors' accuracy and possibly modifying them.

Response: We continuously examine the performance of quality measures and revise measures, including risk adjustment, to optimize measurement of quality ensuring that our measures and their components are accurate. We also continue to seek stakeholder input as we conduct our internal measure maintenance work. Further, we agree that education is important and necessary to help SNFs, as well as other PAC settings, understand how the four proposed functional outcome measures will be calculated. To that end, we intend to provide training materials through the CMS webinars, open door forums, and help desk support. The expected scores are calculated using the results of our risk-adjustment models. During our May 2016 TEP, we discussed the risk adjustment models extensively, and these discussions included a review of our analyses of the mean admission, discharge and change for the self-care and mobility scores for each risk adjustor. We also reviewed the risk adjustors for competing measures. These discussions are summarized in the SNF Function Summary TEP report, which is 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 believe the risk adjustment model is methodologically strong.

Comment: One commenter generally supported the proposed risk adjustment approach for the four proposed functional outcome measures, but requested additional items to address social risk, such as Medicare-Medicaid status. The commenter recommended testing of the risk adjustment methodology to ensure it adjusts for meaningful differences. Another commenter suggested that we risk adjust the four proposed functional outcome measures for social and environmental factors, such as social support and an accessible home environment. The commenter stated that by not adjusting for social and environmental risk factors, we might be creating conflicting incentives between functional improvement and resource use measures. Another commenter supported the use of other assessment data, such as mode of communication and gateway processes. One commenter expressed support for the proposed risk adjustors for the functional outcome measures, but recommended that we reassess all risk adjusters once the new MDS data are submitted.

Response: We selected the risk factors based on literature review, clinical relevance, TEP input, and empirical findings from the PAC–PRD analyses. For a discussion of social risk factors in the SNF QRP, we refer the commenter to section III.D.2.b.1. of this rule. We agree with the importance of testing and continuously monitoring the risk adjustment models so that the functional outcome quality measures reflect true differences in the effectiveness of treatments provided by SNFs. We will continue to examine the performance of our quality measures and revise risk adjustment approaches as necessary to optimize quality measurement.

Comment: Several commenters supported the use of selected risk adjustors and specifically noted that they support risk adjustors in the areas of age, admission function score, medical conditions, and impairments. One commenter stated that the proposed list of comorbidities used for risk adjustment of the functional outcome measures appears comprehensive but requested further detail of the source of the comorbidities data and the proposed look-back period for including the comorbidities. One commenter supported the inclusion of prior functioning and prior device use items for risk adjustment in the functional outcome measures but was concerned that the collection of this data will add administrative burden. Some commenters noted that coding for addition risk adjusters might cause additional provider burden. One commenter supported the inclusion of new data elements for risk adjustment, specifically the prior functioning, prior device use, primary medical condition category and prior surgery items, but under the condition that we appropriately account for the additional reporting burden within the SNF PPS rates. Another commenter expressed concern about the accuracy and burden of collecting the items that refer to a time period outside the defined period of the SNF stay. One commenter stated that SNFs would not know what determines the model estimate, and proposed that we provide the benchmark for comparison prior to the fiscal year. In addition, this commenter questioned the use of a statistical model since section GG includes the establishment of goals, arguing outcomes could be compared to the SNF's own established goals. Other commenters requested that we use the median discharge scores instead of the mean values as a way to avoid the impact of outliers on the expected score. Another commenter expressed that poor risk adjustment would penalize SNFs that provide care to medically-complex and socioeconomically disadvantaged residents, and threaten access to care.

Response: We agree with commenters on the importance of risk adjustment as functional outcomes can vary based on residents' demographic and admission clinical status. Risk adjustment allows for the comparison of functional outcomes across SNFs. As with other risk adjustors, both prior functioning and prior device use were identified as important risk adjustors for the functional outcome measures through data analyses. In development of the quality measures, we selected risk-adjustors including comorbidities, and other health and prior functioning items, based on evidence in the literature, stakeholder comments during TEPs, public comment opportunities statistical findings, and input from subject matter experts. As we develop and refine quality measures, we review existing items, listen to feedback from providers, and consider the appropriateness of adding or deleting any items to the MDS. Reduction of burden is an important consideration as we develop and refine quality measures, which includes risk adjustors for outcome measures. We would like to emphasize the importance of risk adjustment as functional outcomes can vary based on residents' demographic and clinical factors. Prior functioning is an important predictor of functional improvement and this is data routinely collected by therapists when developing a resident's care plan.

We agree with the commenter that it is important for risk adjustment of quality measures to be reliable and valid. As mentioned previously, the risk adjustors were determined based on data analysis, stakeholder input, literature review, clinical relevance and public comment. As noted above, we agree with the commenter for the need to re-examine the risk adjustment model when additional data become available. In addition, we appreciate the continued involvement of stakeholders in all phases of measure development and implementation.

We refer the commenter to the Specifications for SNF QRP Quality Measures and Standardized Resident Assessment Data Elements document 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* for additional details about the risk adjustment approach.

With regard to the use of the discharge goals, we would like to note that the quality measure, Application of Percent of Long-Term Care Hospital Patients with an Admission and Discharge Functional Assessment and a Care Plan that Addresses Function (NQF #2631), requires documentation of only one goal. Using goals to determine outcomes would require SNFs to complete all goals in section GG, which would add significant burden. With regard to the suggestion of using the median rather than the mean value, we will examine this approach as we examine additional data to determine how it affects quality measure scores.

We would like to note that the risk adjustment model for these outcomes includes up to 60 risk-adjusters, and includes more clinically and statistically relevant adjusters for function than other risk-adjusted functional outcomes measures. We will pursue ongoing monitoring and analysis of these proposed functional outcome measures to identify any potential disparities across patient and facility characteristics.

Comment: One commenter was concerned that the PAC PRD data from 34 nursing facilities and other providers used to develop the risk adjustors for the functional outcome measures for SNFs were inadequate. The commenter felt that a larger volume of data is

necessary to verify the current risk adjustors. The commenter recommended that we reevaluate these risk adjustors on a regular basis to ensure their accuracy and to ensure that SNF providers are not evaluated and penalized in the future based on inadequate risk adjustment. The commenter also stated that suggestions offered during a Technical Expert Panel should be tested with data before becoming part of the quality measure and payment system.

Response: As previously discussed, the risk adjustors were selected based on literature review, clinical relevance, Technical Expert Panel input, public comment opportunities, and empirical findings from the data analyses from 60 SNFs and approximately 4,000 resident assessments. Based on our comprehensive approach to developing the models and the alignment between these models and the IRF models, we believe that our models are adequate for risk adjustment for the four SNF functional outcome measures. As part of measure maintenance and evaluation, we routinely analyze data to monitor the performance of implemented quality measures, including risk adjustment models, and thus we agree with the commenter that we should re-examine the risk adjustment model when national data become available. We aim to develop accurate and fair measures and we continuously examine the performance of quality measures and revise measures, including risk adjustment, to optimize measurement of quality.

Comment: Some commenters requested that additional risk adjusters be included in the proposed outcome measures' statistical models, and that each model includes a similar set of risk adjusters. One commenter requested that cognition and age be included in the model, while other commenters were concerned that ''prior functioning: functional cognition'', ''fall history'', and ''prior functioning: mobility'' were not included in the self-care model. Another commenter disagreed with the specification ''independent'' as the reference category since it appeared this also included residents with an unknown prior functional status. The commenter explained that in PAC settings, it is more likely that a patient who cannot report their prior functional status was more dependent rather than more independent before being admitted, so should not be grouped into the ''independent'' reference category.

Response: The majority of risk adjusters are the same in both the self-care and mobility functional outcome models. With regard to the variables included in the mobility models, but not included in the self-care models, these variables were all tested in the self-care model, but they were not statistically significant predictors of the change in self-care scores or the discharge self-care scores. As noted above, we will continue to examine the risk adjustment models when more data become available. We would also like to clarify that cognition and age are included in risk adjustment models and that the Brief Interview for Mental Status (BIMS) specifically accounts for functional variation associated with cognition status. Regarding the reference group ''independent'' for the prior functional status risk adjustors, we appreciate the commenter's suggestion and will take it into consideration.

Comment: Several commenters requested additional information regarding coding of some of the risk adjustment variables. One commenter requested additional detail about how a SNF would identify the appropriate primary medical condition category for the proposed new MDS item I0020, which is used for risk adjustment of the functional outcome measures. The commenter stated that the current approach of requiring the provider to identify one of the 13 primary medical diagnoses or list an ICD–10 code is burdensome and suggested rather a provider should enter the applicable ICD–10 code onto the MDS, which would then be mapped by the MDS grouper software to identify the applicable condition. The commenter further stated that the admitting diagnosis for admission to a SNF may not be directly relevant to the diagnosis associated with mobility and self-care treatment plans and goals, unlike with IRFs, and recommended that we revise this section of the MDS to request providers report the primary medical condition associated with mobility and self-care treatment. Another commenter requested more clarification on the use ICD–10 codes in defining the primary medical condition category, and further noted concern that these codes are more prevalent in the IRF setting, compared to the SNF setting. This commenter expressed concern about where the diagnosis group information will come from and explained that ICD–10 coding is complete and requires multiple levels of consideration and clinical input. Another commenter requested information on how ''medically complex'' is defined. Other commenters requested further clarification on where information for items such as mechanical ventilation will be acquired, how ''major surgery'' is defined and how the interaction between primary diagnosis and SNF admission functional status is determined in risk adjustment.

Response: We appreciate the commenters' concerns regarding coding of the primary medical conditions as well as the coding of mechanical ventilation and major surgery for risk adjustment. As previously noted, we intend to provide guidance on these issues as part of our comprehensive training. Some of these variables were added to the IRF–PAI Version 1.4 when the functional outcome measures were adopted in the IRF QRP, and since these primary medical conditions will be aligned across the IRF and SNF settings, providers can get a preview of the coding guidance and definitions in the IRF PAI Training Manual on page J–5, which is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/IRF-Quality-Reporting/IRF-PAI-and-IRF-QRP-Manual.html.* The RAI manual will also be updated with all timely and accurate information. With regard to the primary medical condition diagnosis, which are risk adjustors for the four functional outcome measures, the proposed MDS effective October 1, 2018 does include primary diagnosis as a data element.

Comment: One commenter noted that the use of the term ''Primary rehabilitation diagnosis'' does not recognize that not all patients are admitted for rehabilitation.

Response: We would like to clarify that the term ''Primary rehabilitation diagnosis'' is not used as part of the four proposed functional outcome measures.

Comment: One commenter supported the use of the BIMS for risk adjustment of the functional outcome measures, stating that learning and memory deficits can significantly impact the rehabilitation of residents with functional impairments. However, the commenter stated that the BIMS is designed as a resident interview and that the use of the BIMS alone as risk adjustment in the SNF setting would be problematic due to the high percentage of residents unable to complete the BIMS as a result of severe cognitive or physical impairments. The commenter stated that a SNF resident's inability to complete the BIMS is often associated with slower rates and lesser degrees of functional improvement than those residents that can complete the BIMS. This commenter requested clarification as to how we will address risk adjustment for these residents and suggested excluding SNF residents that cannot complete the BIMS items if they are not accounted for in the current risk adjustment model. The commenter also

suggested development of standardized patient assessment data for clinician observation of cognitive function and mental status in the future to account for residents who are unable to complete the BIMS.

Response: We appreciate the commenter's feedback regarding the use of the BIMS in risk adjustment for the functional outcome measures. We would like to clarify that in the MDS 3.0, if a resident is unable to complete the BIMS, the provider is directed to administer the Staff Assessment for Mental Status (C0700–C1000), and the data from the staff assessment for mental status is used for cognitive status risk adjustment when the BIMS score is not available. With regard to the residents who are unable to be interviewed for the BIMS due to communication disorders, the BIMS can also be administered in writing. Further, we note that communication impairment is also a risk adjusters the self-care and mobility models. With regard to the residents who are unable to be interviewed for the BIMS due to communication disorders, we note that communication impairment is also a risk adjusters the self-care and mobility models.

Comment: MedPAC noted the importance of using a consistent definition for ''at admission'' to enable accurate comparisons across PAC providers. The commenter stated that we should require that the assessment be completed within 3 days of admission and stated that the Day-5 assessment in SNFs is problematic since it can be conducted between Day 1 and Day 8.

Response: We appreciate the importance of data collection within consistent assessment time frames and we maintain a consistent approach to collecting information on or as close to the time of admission as possible. For example, on the 5-day assessment in SNF, the assessment time frame for the section GG Self-Care and Mobility data items on the MDS is 3 calendar days at the time of admission (first 3 calendar days) and discharge (day of discharge and the 2 days prior to the day of discharge). Therefore, across all PAC assessment instruments, we are collecting on a patient's usual performance within that three-day time period. That is, the 3-day assessment time frame for the section GG Self-Care and Mobility data elements is standardized across the three institutional PAC settings, SNFs, IRFs and LTCHs.

Comment: Two commenters requested that we ensure that the four quality measures are consistently reviewed for reliability, accuracy, and applicability to patients in different PAC settings to develop standards to compare quality across PAC settings. The commenters requested that we consider whether variation in training and practices among providers in various PAC settings affects data entry processes for the MDS and other PAC instruments, and whether this undermines the comparability of the proposed functional outcome measures. Another commenter requested that we provide clear language that cross-setting applications are not valid at this time due to differences in patient populations, payment policy, and specific measure calculation details. One commenter voiced concern that additional time, testing, and training may be necessary to ensure measures are implemented consistently across different settings that use very different processes, scales, definitions, and time frames, to allow data to be comparable across settings.

One commenter requested that we use the same set of definitions for standardized and interoperable functional assessment data in each PAC setting. The commenter further stated that this would mitigate providers collecting and calculating data for these measures differently across settings. The commenter was concerned discrepancies could result in unintended consequences with regard to payment and public reporting.

Response: We agree with the commenters that the accurate collection of functional assessment data is important across all PAC settings. Providers are required to submit accurate data to us, and we provide training and other resources. Providers should collect data in a manner that fits with the clinical workflow within their facility. With regard to the concern that reporting variability may impact comparability across facilities, we agree that comprehensive training is needed to ensure accuracy of data collection and interpretation as well as successful implementation of new measures. As with previous measures, we will provide training sessions, training manuals, Webinars, open door forums, help desk support, and a Web site that hosts training information (*http://www.youtube.com/user/CMSHHSgov*). At this time, we are adopting these measures into the SNF QRP, which is a pay-for-reporting program, and have not specified a timeframe for public reporting of these measures for SNFs.

With regard to the request for standardized and interoperable functional assessment data in each PAC setting, we agree with the commenter about the importance of accurate collection of standardized patient assessment data across the PAC settings. The item definitions are the same across PAC settings, and we continue to work to harmonize the coding guidance for the standardized assessment data elements as we believe that this is key to the collection of accurate data.

Comment: One commenter supported our proposal to collect data on the proposed function quality measures through the MDS using the QIES ASAP system.

Response: We appreciate the commenter's support.

Final Decision: After careful consideration of the public comments received, we are finalizing our proposal to adopt the four functional outcome measures, Application of IRF Functional Outcome Measure: Change in Self-Care Score for Medical Rehabilitation Patients (NQF #2633), Application of IRF Functional Outcome Measure: Change in Mobility Score for Medical Rehabilitation Patients (NQF #2634), the Application of IRF Functional Outcome Measure: Discharge Self-Care Score for Medical Rehabilitation Patients (NQF #2635), the Application of IRF Functional Outcome Measure: Discharge Mobility Score for Medical Rehabilitation Patients (NQF #2636), beginning with the FY 2020 SNF QRP.

h. Modifications to Potentially Preventable 30-Day Post-Discharge Readmission Measure for Skilled Nursing Facility (SNF) Quality Reporting Program (QRP)

In the FY 2017 SNF PPS final rule (81 FR 52030 through 52034), we adopted the Potentially Preventable 30-Day Post-Discharge Readmission Measure for SNF QRP. This measure was developed to meet section 1899B(d)(1)(C) of the Act, which calls for measures to reflect all-condition risk-adjusted potentially preventable hospital readmission rates for PAC providers, including SNFs.

This measure was specified to be calculated using 1 year of Medicare FFS claims data; however, in the FY 2018 SNF PPS proposed rule (82 FR 21057) we proposed to increase the measurement period to 2 years of claims data. The rationale for this change is to expand the number of SNFs with 25 stays or more, which is the minimum number of stays that we require for public reporting. Furthermore, this modification will align the SNF measure more closely with other potentially preventable hospital readmission measures developed to meet the IMPACT Act requirements and adopted for the IRF and LTCH QRPs, which are

calculated using 2 consecutive years of data.

We also proposed to update the dates associated with public reporting of SNF performance on this measure. In the FY 2017 SNF PPS final rule (81 FR 52030 through 52034), we finalized initial confidential feedback reports by October 2017 for this measure based on 1 calendar year of claims data from discharges during CY 2016 and public reporting by October 2018 based on data from CY 2017. However, to make these measure data publicly available by October 2018, we proposed to shift this measure from calendar year to fiscal year, beginning with publicly reporting on claims data for discharges in fiscal years 2016 and 2017.

Additional information regarding the Potentially Preventable 30-Day Post-Discharge Readmission Measure for SNF QRP can be found 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 sought public comment on our proposal to increase the length of the measurement period and to update the public reporting dates for this measure. A discussion of these comments, along with our responses, appears below.

Comment: We received several comments on our proposal to expand the data reporting period for SNFs from one year to 2 years for the Potentially Preventable 30-Day Post-Discharge Readmission Measure for SNF QRP. MedPAC and other commenters supported this proposal because it would increase the number of SNFs included in public reporting. Other commenters expressed support for aligning the SNF measure with the potentially preventable hospital readmission measures we have adopted for the IRF and LTCH QRPs, which also use 2 years of data.

Some commenters were concerned that the greater lag associated with expanding the reporting period to 2 years would make the measure less valuable or sensitive to quality improvement. One commenter was concerned that publicly reporting performance data based on 2 years of data may not accurately reflect the quality of care that SNFs are currently furnishing. Some commenters were opposed to the proposal because it would not align with measurement periods used in other SNF quality measures. One commenter was specifically opposed to shifting this measure to a fiscal year cycle because most SNF data are based on calendar years, noting that inconsistent time periods may create confusion. Another commenter did not oppose the shift to fiscal year as long as confidential feedback reports and review and correction timelines would not be negatively impacted.

Response: We appreciate commenters' concerns that increasing the measurement period from one year to 2 years would create a greater delay between data collection and public reporting of this measure. However, we agree with those commenters that noted the benefit of increasing the number of SNFs for public reporting purposes outweighs the concerns associated with the data delays. We also agree with commenters that this change would better align the SNF measure with the other PPR measures developed to meet the requirements of the IMPACT Act. We also note that changing the public reporting dates for this measure from calendar to fiscal year will not impact providers' confidential feedback reports or the length of time they have to review and correct the data to be made publicly available.

Final Decision: After careful consideration of the public comments, we are finalizing our proposal to increase the measurement period from 1 year to 2 years for the calculation of the Potentially Preventable 30-day Post-Post Discharge Readmission Measure for SNF QRP measure. We are also finalizing our proposal to shift from calendar to fiscal years for public reporting of this measure.

i. SNF QRP Quality Measures Under Consideration for Future Years

In the FY 2018 SNF PPS proposed rule (82 FR 21058), we invited public comment on the importance, relevance, appropriateness, and applicability of each of the quality measures listed in Table 19 for future years in the SNF QRP.

TABLE 19—SNF QRP QUALITY MEASURES UNDER CONSIDERATION FOR FUTURE YEARS

NQS Priority	Patient- and Caregiver-Centered Care
Measure	• Application of Percent of Residents Who Self-Report Moderate to Severe Pain.
NQS Priority	Health and Well-Being
Measure	• Application of 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.
NQS Priority	Communication and Care Coordination
Measure	• Modification of the Discharge to Community-Post Acute Care (PAC) Skilled Nursing Facility (SNF) Quality Reporting Program (QRP) measure.

We are also considering a measure focused on pain that relies on the collection of patient-reported pain data, and another measure regarding the Percent of Residents Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine. Finally, we are considering a measure related to patient safety, that is, Patients Who Received an Antipsychotic Medication.

Commenters submitted the following comments related to the proposed rule's discussion of the SNF QRP Quality Measures Under Consideration for Future Years. A discussion of these comments, along with our responses, appears below.

Comment: One commenter supporting the future measure concept of the percent of residents who self-report moderate to severe pain, suggested inclusion of this measure by FY 2019 at the latest. Another commenter suggested

that they do not believe that pain experience alone should be a quality measure, expressing that the presence of pain does not provide enough information to help an individual's overall quality of life improve.

One commenter suggested that a measure be developed that reflects patient-centered care pain management regardless of ability to self-report as a significant portion of SNF residents are not able to self-report pain and suggested using reliable and valid observational assessment items such as those in the current MDS 3.0 Section J0800 and J0850. The commenter encouraged us to consider incorporating the standardized observational pain assessment data elements that are currently being developed and tested to fulfill the requirements of the IMPACT Act. The commenter also urged us to seek NQF endorsement for any new measures to be incorporated into the SNF QRP program. Another commenter encouraged assessment for communication about pain rather than experience of pain without inadvertently incentivizing the use of opioid medications in alignment with proposed changes to HCAHPS. Another commenter suggested modifying this measure to reflect the proportion of residents for which moderate to severe pain interferes with or prevents important daily functional tasks and drive improvements in quality of life.

Response: We appreciate the comments pertaining to the Application of Percent of Residents Who Self-Report Moderate to Severe Pain (Short Stay) (NQF #0676) measure under consideration for future implementation in the SNF QRP. We note that appropriately assessing pain as an outcome is important, acknowledge the importance of avoiding unintended consequences that may arise from such assessments, and will take into consideration the commenters' recommendations. We would like to note that our goal is to submit all fully developed measures to NQF for consideration of endorsement.

Comment: We received several comments supporting the development of a seasonal influenza vaccine measure appropriate for the SNF population. One commenter stated that the incidence and impact of influenza disease is severe within the population of older adults in a SNF setting, and stated that as a result, there is a need for this measure. One commenter further suggested that a measure of this type presents an important opportunity to promote higher quality and more efficient health care for Medicare beneficiaries. One commenter recommended that we give due consideration to the cost of these services when the costs (for example, the purchase of the vaccine) of these services are bundled into the SNF Part A payment rates. This commenter supported alignment with ongoing efforts to collect and report this measure in the Long-Term Care Hospital Quality Reporting Program (LTCH QRP). Further, this commenter suggested CMS may want to add a pneumococcal vaccine measure in addition to an influenza measure.

Response: We acknowledge the commenters' support of inclusion of a seasonal influenza vaccine measure. We will take all recommendations into consideration in our ongoing efforts to identify and propose appropriate measures for the SNF QRP.

Comment: We received general support for development of an antipsychotic medication measure appropriate for the SNF population. One commenter expressed support for this measure concept and suggested inclusion of the measure by FY 2019 at the latest. One commenter expressed support for including most individuals in the measure regardless of dementia diagnoses. However, this commenter further suggested that Food and Drug Administration (FDA) approved indications of the medications should be excluded from this measure. Another commenter suggested further development of the measure as there is no existing baseline measurement. Another commenter suggested that any future measure should account for informed choices by persons with behavioral and psychotic symptoms of dementia (BPSD) and their families regarding the use of antipsychotic medications for appropriately-used antipsychotics, even if the medication does not have an indication approved by the FDA for their symptoms.

Response: We acknowledge the support of inclusion of an antipsychotic measure and note the suggestion pertaining to the exclusions as well as the measure accounting for persons with BPSD. Recommendations will be taken into consideration in our ongoing efforts to identify and propose appropriate measures for the SNF QRP in the future.

Comment: MedPAC suggested that we consider the adoption of future measures that can assess providers' ability to maintain function and prevent functional decline. MedPAC noted that the two quality measures for change in function do not capture whether a provider can maintain function as residents with conditions who are not expected to improve or who are already independent are excluded from the four measures that we are finalizing.

Response: We agree with MedPAC that future quality measurement work should include the development of quality measures that focus on maintaining function and prevention of functional decline. We appreciate MedPAC's concern regarding the exclusion of residents who are not expected to improve due to certain medical conditions or who are independent. We would like to point out that two of the measures we are adopting in this final rule for the SNF QRP, Application of the IRF Function Outcome Measure: Discharge Self-Care Score for Medical Rehabilitation Patients (NQF #2635) and Application of the IRF Function Outcome Measure: Discharge Mobility Score for Medical Rehabilitation Patients (NQF #2636), capture residents who are independent with function at admission. In that situation, maintenance of independence for the section GG self-care or mobility activities would apply to these residents.

Comment: One commenter recommended the addition of a quality measure of maintenance of functional status to the SNF QRP to address requirements of the Jimmo Settlement. The commenter noted that functional improvement is not a goal for all residents receiving rehabilitation; for some residents, maintaining or slowing functional decline is a goal.

Response: We appreciate the commenter's suggestions, and we will consider this recommendation in future measure development.

Comment: One commenter encouraged us to consider the importance of instrumental activities of daily living as a measurement construct for assessing patient need, monitoring quality, and affecting care and payment, stating that instrumental activities of daily living performance is critical to maintaining safety and avoiding readmissions.

Response: We appreciate the commenter's suggestions for future measures and we will consider this recommendation in future measure development.

Comment: MedPAC commented that while the proposed future measures capture important dimensions of SNF care, MedPAC prefers that Medicare hold providers accountable for claims-based outcome measures. Several commenters suggested further development and standardization of outcome measures to compare and contrast between PAC settings and to assess short- and long-term patient status post injury or illness. One

commenter suggested moving away from an emphasis on process measures toward more outcome-related measures. Another commenter added that any additional vaccination measure give due consideration to the cost of these services. Others suggested measures related to consumer satisfaction following short stay rehabilitation and discharge home. One commenter suggested that any patient experience of care survey for SNFs be economical in its approach and carefully aligned with other surveys to reduce duplicative collection activities. Other commenters suggested a number of additional measures for inclusion in the SNF QRP. One commenter suggested that we consider developing measures to assess quality of life and long-term functional outcomes such as community-oriented factors including ability to live independently, return to work (where appropriate), community participation and social interaction. Another commenter suggested workforce related measures such as staffing quality metrics from payroll-based journal staffing and collection such as staff turnover, nursing staff hours per resident stay and CNA hours per resident stay. The commenter further recommended measures that include language related to initiating palliative care and making ethical considerations regarding continuing or terminating complex medical care. The commenter also suggested incorporating coordination and collaboration on patient, family, and medical goals of care as well as assessment of family members' and caregivers' capacity to assume patient care post-discharge. Another commenter further recommended that measures such as those currently reported on Nursing Home Compare be used in the interim until more post-acute care cross-setting measures are developed.

Response: We appreciate the input from MedPAC and other commenters for their suggestions on future measure concepts as well as on the interim use of measures currently reported on Nursing Home Compare. With all measures, we seek to fulfill the mandate of the IMPACT Act to align across settings and will take these comments into consideration as we further develop measures for use in the SNF QRP.

(1) IMPACT Act Measure—Possible Future Update to Measure Specifications

In the FY 2017 SNF PPS final rule (81 FR 52021 through 52029), we finalized the Discharge to Community-Post Acute Care (PAC) Skilled Nursing Facility (SNF) Quality Reporting Program (QRP) measure, which 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. We received public comments (see 81 FR 52025 through 52026) recommending exclusion of baseline nursing facility residents from the measure, as these residents did not live in the community prior to their SNF stay. At that time, we highlighted that using Medicare FFS claims alone, we were unable to accurately identify baseline nursing facility residents. We stated that potential future modifications of the measure could include assessment of the feasibility and impact of excluding baseline nursing facility residents from the measure through the addition of patient assessment-based data. In response to these public comments, we are considering a future modification of the Discharge to Community-PAC SNF QRP measure, which would exclude baseline nursing facility residents from the measure. Further, this measure is specified to be calculated using one year of Medicare FFS claims data. We are considering expanding the measurement period in the future to two consecutive years of data to increase SNF sample sizes and reduce the number of SNFs with fewer than 25 stays that would otherwise be excluded from public reporting. This modification would also align the measurement period with that of the discharge to community measures adopted for the IRF and LTCH Quality Reporting Programs to meet the IMPACT Act requirements; both the IRF and LTCH measures have measurement periods of two consecutive years.

We sought public comment on these considerations for Discharge to Community-PAC SNF QRP measure in future years of the SNF QRP. A discussion of these comments, along with our responses, appears below.

Comment: Multiple commenters expressed support for excluding baseline nursing facility residents from the discharge to community measure as a potential future measure modification. Commenters stated that this exclusion would result in the measure more accurately portraying quality of care provided by SNFs, while controlling for factors outside of SNF control.

Response: We acknowledge the commenters' support for the potential exclusion of baseline nursing facility residents as a future measure modification. We will consider their views and determine whether to propose to exclude baseline nursing facility residents from the Discharge to Community-PAC SNF QRP measure in future years of the SNF QRP.

Comment: MedPAC supported expanding the Discharge to Community-PAC SNF QRP measurement period from 1 year to 2 years, acknowledging that it is important to include as many providers in public reporting as possible and that expansion to 2 years is a good strategy to help include more low-volume providers in public reporting. A few commenters opposed expansion of the measurement period to 2 years, expressing concern that it decreased the timeliness of the data and actionability for providers to drive change in quality or process improvement. One commenter expressed concern that the expansion would misalign the measurement period with that of other SNF measures in use, and that inclusion of older data would decrease sensitivity to change in quality, particularly for high volume SNFs. This commenter stated that a 2-year window would not accurately reflect recent improvement or decline in discharge planning practices, resulting in inaccurate portrayal of the current quality of care furnished by a SNF. Another commenter expressed concern that a two-year measurement period penalized facilities with adverse ratings for longer periods of time.

Response: We acknowledge MedPAC for its support for possible expansion of the Discharge to Community-PAC SNF QRP measurement period to 2 years in future years of the SNF QRP. We would like to clarify that we did not propose this change, but are considering it for future years. We also acknowledge commenters' concerns about expanding the measurement period to 2 years. We will consider these views and determine whether to propose expanding the Discharge to Community-PAC SNF QRP measurement period from 1 year to 2 years in future years of the SNF QRP.

(2) IMPACT Act Implementation Update

As a result of the input and suggestions provided by technical experts at the TEPs held by our measure developer, and through public comment, we are engaging in additional development work for two measures that would satisfy the domain of accurately communicating the existence of and providing for the transfer of health information and care preferences when the individual transitions, in section 1899B(c)(1)(E) of the Act, including performing additional testing. The measures under development are: *Transfer of Information at Post-Acute Care Admission, Start or Resumption of Care from other Providers/Settings;* and *Transfer of Information at Post-Acute Care Discharge, and End of Care to*

other Providers/Settings. We intend to specify these measures under section 1899B(c)(1)(E) of the Act no later than October 1, 2018 and we intend to propose to adopt them for the FY 2021 SNF QRP, with data collection beginning on or about October 1, 2019.

Commenters submitted the following comments related to the proposed rule's discussion of the IMPACT Act Implementation Update. A discussion of these comments, along with our responses, appears below.

Comment: One commenter suggested that we be cautious in our development of the Transfer of Health Information measure set and only proceed to propose and adopt measures that receive NQF endorsement. This commenter cited concerns about the measure development, citing the 2016 MAP PAC/LTC meeting. A commenter supported our efforts to promote coordination of care across the care continuum, and commented that the transfer of accurate health information—including resident preferences, care plan, and other information—is essential to quality outcomes for residents. A commenter expressed appreciation that we are developing measures that will help facilitate the accurate communication of a person's health information and care preferences across the continuum of care and believes that these measures will facilitate better care coordination and outcomes. The commenter also appreciated that we have engaged providers and consumers in the development of these measures and encourages us to develop measures that represent a balance between the volume and detail of information exchanged and reported, and the underlying administrative burdens the measures may create. The commenter noted that the burden is particularly important for small and rural providers that may have more challenges with technology-driven information exchange because health information technology incentive programs for hospitals and physicians have not been extended to SNF providers.

Response: We appreciate the comments and feedback on the Transfer of Health Information measures that are currently under development. We also appreciate the recognition that we have engaged providers and consumers in the development of these measures. As we continue to develop these measures, we will consider this feedback. We would like to clarify that the measure under development does not currently require the adoption of health IT and electronic means of information transfer. We intend to re-submit these measures, once fully specified and tested, for review to the MAP PAC/LTC Workgroup. Further, we plan to submit the measures to the NQF for consideration for endorsement when we believe the measures are ready for NQF review.

j. Standardized Resident Assessment Data Reporting for the SNF QRP

(1) Standardized Resident Assessment Data Reporting for the FY 2019 SNF QRP

Section 1888(e)(6)(B)(i)(III) of the Act requires that for fiscal year 2019 and each subsequent year, SNFs report standardized resident assessment data required under section 1899B(b)(1) of the Act. As we describe in section III.D.2.g.(1) above, we are finalizing in this final rule that the current pressure ulcer measure, Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short Stay) (NQF #0678), will be replaced with the proposed pressure ulcer measure, Changes in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury, beginning with the FY 2020 SNF QRP. The current pressure ulcer measure will remain in the SNF QRP until that time. Accordingly, for the requirement that SNFs report standardized resident assessment data for the FY 2019 SNF QRP, we proposed that the data elements used to calculate that measure meet the definition of standardized resident assessment data for medical conditions and co-morbidities under section 1899B(b)(1)(B)(iv) and that the successful reporting of that data under section 1888(e)(6)(B)(i)(II) for admissions as well as discharges occurring during fourth quarter CY 2017 would also satisfy the requirement to report standardized resident assessment data for the FY 2019 SNF QRP.

The collection of assessment data pertaining to skin integrity, specifically pressure related wounds, is important for multiple reasons. Clinical decision support, care planning, and quality improvement all depend on reliable assessment data collection. Pressure related wounds represent poor outcomes, are a serious medical condition that can result in death and disability, are debilitating, painful and are often an avoidable outcome of medical care.[38] [39] [40] [41] [42] [43] Pressure related wounds are considered health care acquired conditions.

As we note above, the data elements needed to calculate the current pressure ulcer measure are already included on the MDS and reported for SNFs, and exhibit validity and reliability for use across PAC providers. Item reliability for these data elements was also tested for the nursing home setting during implementation of MDS 3.0. Testing results are from the RAND Development and Validation of MDS 3.0 project.[44] The RAND pilot test of the MDS 3.0 data elements showed good reliability and is also applicable to both the IRF–PAI and the LTCH CARE Data Set because the data elements tested are the same. Across the pressure ulcer data elements, the average gold-standard nurse to gold-standard nurse kappa statistic was 0.905. The average gold-standard nurse to facility-nurse kappa statistic was 0.937. Data elements used to risk adjust this quality measure were also tested under this same pilot test, and the gold-standard to gold-standard kappa statistic, or percent agreement (where kappa statistic not available), ranged from 0.91 to 0.99 for these data elements. These kappa scores indicate ''almost perfect'' agreement using the Landis and Koch standard for strength of agreement.[45]

The data elements used to calculate the current pressure ulcer measure received public comment on several occasions, including when that measure was proposed in the FY 2012 IRF PPS (76 FR 47876) and IPPS/LTCH PPS proposed rules (76 FR 51754). Further, they were discussed in the past by TEPs held by our measure development contractor on June 13 and November 15, 2013, and recently by a TEP on July 18, 2016. TEP members supported the measure and its cross-setting use in PAC. The report, *Technical Expert Panel Summary Report: Refinement of the Percent of Patients or Residents with*

[38] Casey, G. (2013). ''Pressure ulcers reflect quality of nursing care.'' *Nurs N Z* 19(10): 20–24.

[39] Gorzoni, M.L. and S.L. Pires (2011). ''Deaths in nursing homes.'' *Rev Assoc Med Bras* 57(3): 327–331.

[40] Thomas, J.M., et al. (2013). ''Systematic review: health-related characteristics of elderly hospitalized adults and nursing home residents associated with short-term mortality.'' *J Am Geriatr Soc* 61(6): 902–911.

[41] White-Chu, E.F., et al. (2011). ''Pressure ulcers in long-term care.'' *Clin Geriatr Med* 27(2): 241–258.

[42] Bates-Jensen, B.M. Quality indicators for prevention and management of pressure ulcers in vulnerable elders. *Ann Int Med.* 2001;135 (8 Part 2), 744–51.

[43] Bennet, G, Dealy, C, Posnett, J (2004). The cost of pressure ulcers in the UK, *Age and Aging,* 33(3):230–235.

[44] Saliba, D., & Buchanan, J. (2008, April). *Development and validation of a revised nursing home assessment tool: MDS 3.0.* Contract No. 500–00–0027/Task Order #2. Santa Monica, CA: Rand Corporation. Retrieved from *http://www.cms.hhs.gov/NursingHomeQualityInits/Downloads/MDS30FinalReport.pdf.*

[45] Landis, R., & Koch, G. (1977, March). The measurement of observer agreement for categorical data. *Biometrics* 33(1), 159–174.

Pressure Ulcers that are New or Worsened (Short-Stay) (NQF #0678) Quality Measure for Skilled Nursing Facilities (SNFs), Inpatient Rehabilitation Facilities (IRFs), Long-Term Care Hospitals (LTCHs), and Home Health Agencies (HHAs), is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

We sought public comment on this proposal. A discussion of these comments, along with our responses, appears below.

Comment: We received many comments in support of reporting the data elements already implemented in the SNF QRP to fulfill the requirement to report standardized resident assessment data for the FY 2019 SNF QRP. Specifically, many commenters supported the use of data elements used in calculation of the Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short Stay) (NQF #0678) to fulfill this requirement.

Response: We appreciate the commenter's support of the proposal.

Final Decision: After consideration of the public comments received, we are finalizing the proposal that the data elements currently reported by SNFs to calculate the current measure, Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short Stay) (NQF #0678), meet the definition of standardized resident assessment data for medical conditions and co-morbidities under section 1899B(b)(1)(B)(iv) of the Act, and that the successful reporting of that data under section 1888(e)(6)(B)(i)(II) of the Act would also satisfy the requirement to report standardized resident assessment data under section 1888(e)(6)(B)(i)(III) of the Act.

(2) Standardized Resident Assessment Data Reporting Beginning With the FY 2020 SNF QRP

In the FY 2018 SNF PPS proposed rule (82 FR 21059 through 21076), we described our proposals for the reporting of standardized resident assessment data by SNFs beginning with the FY 2020 SNF QRP. SNFs would be required to report these data for SNF admissions at the start of the Medicare Part A stay and SNF discharges at the end of the Medicare Part A stay that occur between October 1, 2018 and December 31, 2018, with the exception of two data elements (Hearing and Vision), which would be required for SNF admissions at the start of the Medicare Part A stay only that occur between October 1, 2018, and December 31, 2018. Following the initial reporting year for the FY 2020 SNF QRP, subsequent years for the SNF QRP would be based on a full calendar year of such data reporting.

In selecting the data elements, we carefully weighed the balance of burden in assessment-based data collection and aimed to minimize additional burden through the utilization of existing data in the assessment instruments. We also note that the resident assessment instruments are considered part of the medical record, and sought the inclusion of data elements relevant to resident care. We also took into consideration the following factors for each data element: overall clinical relevance; ability to support clinical decisions, care planning and interoperable exchange to facilitate care coordination during transitions in care; and the ability to capture medical complexity and risk factors that can inform both payment and quality. Additionally, the data elements had to have strong scientific reliability and validity; be meaningful enough to inform longitudinal analysis by providers; had to have received general consensus agreement for its usability; and had to have the ability to collect such data once but support multiple uses. Further, to inform the final set of data elements for proposal, we took into account technical and clinical subject matter expert review, public comment and consensus input in which such principles were applied. We also took into account the consensus work and empirical findings from the PAC PRD. We acknowledge that during the development process that led to these proposals, some providers expressed concern that changes to the MDS to accommodate standardized resident assessment data reporting would lead to an overall increased reporting burden. However, we note that there is no additional data collection burden for standardized data already collected and submitted on the quality measures.

Comment: Many commenters expressed significant concerns with respect to our standardized resident assessment data proposals. Several commenters stated that the new standardized resident assessment data reporting requirements will impose significant burden on providers, given the volume of new standardized resident assessment data elements that were proposed to be added to the MDS. Several commenters noted that the addition of the proposed standardized resident assessment data elements would require hiring more staff, retraining staff on revised questions or coding guidance, and reconfiguring internal databases and EHRs. Other commenters expressed concerns about the gradual but significant past and future expansion of the MDS through the addition of standardized resident assessment data elements and quality measures, noting the challenge of coping with ongoing additions and changes.

Several commenters expressed concern related to the implementation timeline in the proposed rule, which would require SNFs to begin collecting the proposed standardized resident assessment data elements in the timeframe stated in the proposed rule. A few commenters noted that CMS had not yet provided sufficient specifications or educational materials to support implementation of the new resident assessments in the proposed timeline.

Several commenters urged CMS to delay the reporting of new standardized resident assessment data elements by at least one year, and to carefully assess whether all of the proposed standardized resident assessment data elements are necessary under the IMPACT Act. Commenters suggested ways to delay the proposals for standardized resident assessment data elements in the categories of Cognitive Function and Mental Status; Special Services, Treatments, and Interventions; and Impairments, including allowing voluntary or limited reporting for a period of time before making comprehensive reporting mandatory, and delaying the beginning of mandatory data collection for a period of time. Some commenters recommended that during the delay, CMS re-evaluate whether it can require the reporting of standardized resident assessment data in a less burdensome manner.

Response: We understand the concerns raised by commenters that the finalization of our standardized resident assessment data proposals would require SNFs to spend a significant amount of resources preparing to report the data, including updating relevant protocols and systems and training appropriate staff. We also recognize that we can meet our obligation to require the reporting of standardized resident assessment data with respect to the categories described in section 1899B(b)(1)(B) of the Act while simultaneously being responsive to these concerns. Therefore, after consideration of the public comments we received on these issues, we have decided that at this time, we will not finalize the standardized resident

assessment data elements we proposed for three of the five categories under section 1899B(b)(1)(B) of the Act: Cognitive Function and Mental Status; Special Services, Treatments, and Interventions; and Impairments. Although we believe that the proposed standardized resident assessment data elements would promote transparency around quality of care and price as we continue to explore reforms to PAC payment system, the data elements that we proposed for each of these categories would have imposed a new reporting burden on SNFs. We agree that it would be useful to evaluate further how to best identify the standardized resident assessment data that would satisfy each of these categories; would be most appropriate for our intended purposes including payment and measure standardization; and can be reported by SNFs in the least burdensome manner. As part of this effort, we intend to conduct a national field test that allows for stakeholder feedback and to consider how to maximize the time SNFs have to prepare for the reporting of standardized resident assessment data in these categories. We intend to make new proposals with respect to the categories described in sections 1899B(b)(1)(B)(ii), (iii) and (v) of the Act no later than in the FY 2020 SNF PPS proposed rule.

In this final rule, we are finalizing the standardized resident assessment data elements that we proposed to adopt for the IMPACT Act categories of Functional Status and Medical Conditions and Co-Morbidities. Unlike the standardized resident assessment data that we are not finalizing, the standardized resident assessment data that we proposed for these categories are already required to calculate the Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (NQF #0678) quality measure, the Changes in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury quality measure (which we are finalizing in this final rule), and the 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) quality measure (which we finalized in the FY 2016 SNF PPS final rule). As a result, we do not believe that finalizing these proposals creates a new reporting burden for SNFs or otherwise necessitates a delay.

Comment: Several commenters expressed support for the adoption of standardized resident assessment data elements. A few commenters expressed support for standardizing the definitions as well as the implementation of the data collection effort. Several commenters also supported CMS' goal of standardizing the questions and responses across all PAC settings to help ''enable the data to be interoperable, allowing it to be shared electronically, or otherwise between PAC provider types.'' Another commenter noted full support of the IMPACT Act's goals and objectives and appreciated CMS' efforts to regularly communicate with stakeholders through various national provider calls, convening of stakeholders, and meetings with individual organizations.

Response: We appreciate the support of these proposals, but note that for the reasons explained above, we have decided at this time to not finalize the proposals for three of the five categories under section 1899B(b)(1)(B) of the Act: Cognitive Function and Mental Status; Special Services, Treatments, and Interventions; and Impairments.

Comment: Several commenters stated that there is insufficient evidence demonstrating the reliability and validity of the proposed standardized resident assessment data elements. Some commenters stated that the expanded standardized resident assessment data reporting requirements have not yet been adequately tested to ensure they collect accurate and useful data in this setting. A few commenters stated that six of the items that are currently reported in the MDS would be expanded to include additional sub-elements that SNFs would be required to complete. One of these commenters stated that CMS' conclusion that the collection of these standardized resident assessment data elements in the SNF setting would be feasible and the standardized resident assessment data elements would result in valid and reliable data was based on the current use of these data elements in the MDS and the testing of these data elements in the PAC PRD. One commenter stated that several of the proposed standardized resident assessment data elements that had not been adequately tested were deemed close enough to an item that had been tested in the PAC PRD or in other PAC settings and thus appropriate for implementation.

Response: Our standardized resident assessment data elements were selected based on a rigorous multi-stage process described in the FY 2018 SNF PPS proposed rule (82 FR 21044). In addition, we believe that the PAC PRD testing of many of these data elements provides good evidence from a large, national sample of patients and residents in PAC settings to support the use of these standardized patient/resident assessment data elements in and across PAC settings. However, as noted above, we have decided at this time to not finalize the proposals for three of the five categories under section 1899B(b)(1)(B) of the Act: Cognitive Function and Mental Status; Special Services, Treatments, and Interventions; and Impairments. Prior to making new proposals for these categories, we intend to conduct extensive testing to ensure that the standardized resident assessment data elements we select are reliable, valid and appropriate for their intended use.

Comment: MedPAC supported the addition of standardized resident assessment data elements, but cautioned that measures, when used for risk-adjustment, may be susceptible to inappropriate manipulation by providers. MedPAC believed that CMS may want to consider requiring a physician signature to attest that the reported service was reasonable and necessary and including a statement adjacent to the signature line warning that filing a false claim is subject to treble damages under the False Claims Act.

Response: We acknowledge MedPAC's feedback, and agree with the importance of data integrity within resident assessments. We will explore the suggestions made by MedPAC.

Comment: One commenter noted that the absence of a single source document that identifies the MDS data element, assessment type, allowable item responses, and item responses that could negatively impact SNF QRP performance scores and creates administrative challenges in keeping up to date with measure and item changes. This commenter urged us to provide a single resource for SNF providers to identify each individual MDS 3.0 data element identified by CMS and applicable to the various measures and standardized cross-setting data elements that apply to the SNF QRP. Another commenter urged us to provide detailed guidance and training documents that includes prescriptive coding, similar to what was done for the MDS. Another commenter stressed the importance of timely, appropriate education and training for providers to ensure that there is interoperability following full implementation. Another commenter also believed that standardized resident assessment data collected may be affected by educational level and professional expertise of the evaluator and advocated for fully developed risk-adjusters.

Response: We acknowledge the commenters' feedback with respect to administrative challenges and the desire for detailed guidance and training. In ongoing standardized resident

assessment data element development work, we will continue to be mindful of the administrative challenges that new mandated assessment items will place on providers. We agree with the commenter about the importance of providing clear coding guidelines for the proposed standardized resident assessment data elements for a range of education levels. We are also committed to providing comprehensive training and guidance to providers, for any new data elements, including standardized resident assessment data elements, to ensure the fidelity of the assessment.

Comment: A few commenters sought clarification on interoperability requirements, if and how SNF providers will be required to demonstrate interoperability, and described potential challenges to interoperable data exchange, such as timeframes related to data submission (for example, 14 days after discharge for SNFs) and inconsistencies in how data are captured. One commenter encouraged CMS to consider interoperability standards that promote information exchange utilizing EHRs and to specify which data standards are to be used and how they are to be implemented to ensure consistency across providers. The same commenter recommended that CMS work with EHR vendors and other IT developers to implement changes and to consider the time required for implementing changes adopted in the final rule, which may require adopting timelines that are more extended than what was originally required. Further, two commenters urged CMS to develop methods to incentivize providers who are ''stepping up'' and adopting health information technology (HIT), despite the costs and the absence of a regulatory requirement to do so.

Response: We acknowledge commenters' concerns regarding standardization and interoperability of the proposed standardized resident assessment data elements to meet section 1899B(a)(1)(B) of the Act requirements. We wish to clarify that implementation of the proposed standardized resident assessment data elements is intended to facilitate interoperability. We acknowledge that the provision requires that we make certain resident assessment data standardized and interoperable to allow for the exchange of data among PAC settings and other providers in order to access longitudinal information which will facilitate coordinated care and improved outcomes. While the IMPACT Act requires that the post-acute resident assessment instruments be modified so that certain resident assessment data are standardized and interoperable, it does not require the exchange of electronic health information by such providers. We appreciate the comments surrounding the need for more time for providers to implement the changes necessary in response to such modifications, and have addressed this topic in our proposals within this section.

A full discussion of the standardized resident assessment data elements that we proposed to adopt for the categories described in sections 1899B(b)(1)(B)(ii), (iii) and (v) can be found in the FY 2018 SNF PPS proposed rule (82 FR 21060 through 21076). In light of our decision to not finalize our proposals with respect to these categories, we are not going to address in this final rule the specific technical comments that we received on these proposed data elements. However, we appreciate the many technical comments we did receive specific to each of these data elements, and we will take them into consideration as we develop new proposals for these categories. Below we discuss the comments we received specific to the standardized resident assessment data we proposed to adopt, and are finalizing in this final rule, for the categories of Functional Status and Medical Conditions and Co-Morbidities.

a. Standardized Resident Assessment Data by Category

(1) Functional Status Data

We proposed that the data elements currently reported by SNFs to calculate the measure, Application of Percent of Long-Term Care Hospital Patients with an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function (NQF #2631), would also meet the definition of standardized resident assessment data for functional status under section 1899B(b)(1)(B)(i) of the Act, and that the successful reporting of that data under section 1886(m)(5)(F)(i) of the Act would also satisfy the requirement to report standardized resident assessment data under section 1886(m)(5)(F)(ii) of the Act.

These patient assessment data for functional status are from the CARE Item Set. The development of the CARE Item Set and a description and rationale for each item is described in a report entitled ''The Development and Testing of the Continuity Assessment Record and Evaluation (CARE) Item Set: Final Report on the Development of the CARE Item Set: Volume 1 of 3.'' [46] Reliability and validity testing were conducted as part of CMS' Post-Acute Care Payment Reform Demonstration, and we concluded that the functional status items have acceptable reliability and validity. A description of the testing methodology and results are available in several reports, including the report entitled ''The Development and Testing of the Continuity Assessment Record And Evaluation (CARE) Item Set: Final Report On Reliability Testing: Volume 2 of 3'' [47] and the report entitled ''The Development and Testing of The Continuity Assessment Record And Evaluation (CARE) Item Set: Final Report on Care Item Set and Current Assessment Comparisons: Volume 3 of 3.'' [48] The reports are available on CMS' Post-Acute Care Quality Initiatives Web page at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/CARE-Item-Set-and-B-CARE.html.* For more information about this quality measure, we refer readers to the FY 2016 SNF PPS final rule (80 FR 46444 through 46453).

We sought public comment on this proposal. A discussion of these comments, along with our responses, appears below.

Comment: Several commenters supported the collection of standardized resident assessment data across PAC settings to satisfy the IMPACT Act's functional status data reporting requirement. Some commenters specifically expressed support for our proposal that data elements used to calculate 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) be used to meet the definition of standardized resident assessment data for functional status. One commenter noted that their support of standardized resident assessment data was contingent on not adding to facilities' costs or burden.

Response: We appreciate the commenters' support of the functional status standardized resident assessment data for SNFs. These standardized resident assessment data have the potential to facilitate communication among providers and improve care. With regard to burden and cost, we would like to clarify that the data elements from the quality measure Application of Percent of Long-Term Care Hospital Patients with an

[46] Barbara Gage et al., ''The Development and Testing of the Continuity Assessment Record and Evaluation (CARE) Item Set: Final Report on the Development of the CARE Item Set'' (RTI International, 2012).

[47] Ibid.

[48] Ibid.

Admission and Discharge Functional Assessment and a Care Plan that Addresses Function (NQF #2631) are data elements that are currently being collected on the MDS by SNFs, and therefore, there is no additional burden or cost associated with this reporting.

Comment: One commenter requested that we clarify that reporting on the Discharge Goal items for each mobility and self-care item in the SNF PPS admission assessment is for SNF QRP reporting purposes, and does not require a care plan to be developed for each discharge goal.

Response: The proposal to use the data elements used to calculate the function process quality measure as standardized resident assessment data refers to the admission and discharge performance self-care and mobility items. The adopted measure Application of Percent of Long-Term Care Hospital Patients with an Admission and Discharge Functional Assessment and a Care Plan that Addresses Function (NQF #2631) requires that only one goal be reported for each SNF patient stay, and that the requirement for that quality measure remains unchanged. Reporting one goal on the MDS satisfies the measure numerator care plan criteria. The SNF does not need to provide any further documentation about a resident's care plan.

Final Decision: Based on the evidence provided above, we are finalizing that the data elements currently reported by SNFs to calculate the measure, Application of Percent of Long-Term Care Hospital Patients with an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function (NQF #2631), would also meet the definition of standardized resident assessment data for functional status under section 1899B(b)(1)(B)(i) of the Act, and that the successful reporting of that data under section 1886(m)(5)(F)(i) of the Act would also satisfy the requirement to report standardized resident assessment data under section 1886(m)(5)(F)(ii) of the Act.

(2) Medical Condition and Comorbidity Data

We proposed that the data elements needed to calculate the current measure, Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short Stay) (NQF #0678), and the proposed measure, Changes in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury, meet the definition of standardized resident assessment data for medical conditions and co-morbidities under section 1899B(b)(1)(B)(iv) of the Act, and that the successful reporting of that data under section 1888(e)(6)(B)(i)(II) of the Act would also satisfy the requirement to report standardized resident assessment data under section 1888(e)(6)(B)(i)(III) of the Act.

''Medical conditions and comorbidities'' and the conditions addressed in the standardized resident assessment data used in the calculation and risk adjustment of these measures, that is, the presence of pressure ulcers, diabetes, incontinence, peripheral vascular disease or peripheral arterial disease, mobility, as well as low body mass index, are all health-related conditions that indicate medical complexity that can be indicative of underlying disease severity and other comorbidities.

Specifically, the data elements used in the measure are important for care planning and provide information pertaining to medical complexity. Pressure ulcers are serious wounds representing poor healthcare outcomes, and can result in sepsis and death. Assessing skin condition, care planning for pressure ulcer prevention and healing, and informing providers about their presence in patient transitions of care is a customary and best practice. Venous and arterial disease and diabetes are associated with low blood flow which may increase the risk of tissue damage. These diseases are indicators of factors that may place individuals at risk for pressure ulcer development and are therefore important for care planning. Low BMI, which may be an indicator of underlying disease severity, may be associated with loss of fat and muscle, resulting in potential risk for pressure ulcers. Bowel incontinence and the possible maceration to the skin associated, can lead to higher risk for pressure ulcers. In addition, the bacteria associated with bowel incontinence can complicate current wounds and cause local infection. Mobility is an indicator of impairment or reduction in mobility and movement which is a major risk factor for the development of pressure ulcers. Taken separately and together, these data elements are important for care planning, transitions in services and identifying medical complexities.

In sections III.D.2.g.1. and III.D.2.j.1. of this final rule, we discuss our rationale for proposing that the data elements used in the measures meet the definition of standardized resident assessment data. In summary, we believe that the collection of such assessment data is important for multiple reasons, including clinical decision support, care planning, and quality improvement, and that the data elements assessing pressure ulcers and the data elements used to risk adjust showed good reliability. We solicited stakeholder feedback on the quality measure, and the data elements from which it is derived, by means of a public comment period and TEPs, as described in section III.D.2.g.1. of this final rule.

We sought public comment on this proposal. A discussion of these comments, along with our responses, appears below.

Comment: We received support for the reporting of data elements already implemented in the SNF QRP to satisfy the requirement to report standardized resident assessment data. Specifically, many commenters supported the use of data elements used in calculation of the current measure, Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short Stay) (NQF #0678), or the proposed measure, Changes in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury, to fulfill this requirement.

Response: We appreciate the comments in support of the proposal, and agree that these data elements currently reported by SNFs meet the definition of standardized resident assessment data and satisfy the requirement to report standardized resident assessment data.

Final Decision: After consideration of the public comments we received, we are finalizing as proposed that the data elements currently reported by SNFs to calculate the current measure, Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short Stay) (NQF #0678), and the proposed measure, Changes in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury, meet the definition of standardized resident assessment data for medical conditions and co-morbidities under section 1899B(b)(1)(B)(iv) of the Act, and that the successful reporting of that data under section 1888(e)(6)(B)(i)(II) of the Act would also satisfy the requirement to report standardized resident assessment data under section 1888(e)(6)(B)(i)(III) of the Act.

k. Form, Manner, and Timing of Data Submission Under the SNF QRP

(1) Start Date for Standardized Resident Assessment Data Reporting by New SNFs

In the FY 2016 SNF PPS final rule (80 FR 46455), we adopted timing for new SNFs to begin reporting quality data under the SNF QRP beginning with the FY 2018 SNF QRP. We proposed in the FY 2018 SNF PPS proposed rule (82 FR

21076) that new SNFs will be required to begin reporting standardized resident assessment data on the same schedule.

We sought public comment on the proposal that new SNFs will be required to begin reporting standardized resident assessment data on the same schedule. A discussion of these comments, along with our responses, appears below.

Comment: We received a comment in support of maintaining the same start date policy for both standardized resident assessment data and SNF QRP measures as this creates consistency in reporting.

Response: We appreciate the commenter's support for extending this policy to the standardized resident assessment data under the SNF QRP.

Final Decision: We are finalizing that new SNFs will be required to begin reporting standardized resident assessment data on the same schedule that they are currently required to begin reporting other quality data under the SNF QRP.

(2) Mechanism for Reporting Standardized Resident Assessment Data Beginning With the FY 2019 SNF QRP

Under our current policy, SNFs report data by completing applicable sections of the MDS, and submitting the MDS–RAI to CMS through the QIESASAP system. 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.* In addition to the data currently submitted on quality measures as previously finalized and discussed in section III.D.2.f. of this final rule, in the FY 2018 SNF PPS proposed rule (82 FR 21076) we proposed that SNFs would be required to begin submitting the proposed standardized resident assessment data for SNF Medicare resident admissions and discharges that occur on or after October 1, 2018 using the MDS. Details on the modifications and assessment collection for the MDS for the proposed standardized resident assessment data 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.*

We sought public comments on this proposal. A discussion of these comments, along with our responses, appears below.

Comment: A commenter expressed support for maintaining the same data submission mechanism policy for submitting both standardized resident assessment data and data on SNF QRP measures, as this facilitates consistency in reporting.

Response: We appreciate the commenter's support.

Final Decision: We are finalizing that beginning with the FY 2019 SNF QRP, SNFs will be required to begin submitting standardized resident assessment data for SNF Medicare resident admissions and discharges that occur on or after October 1, 2018 using the MDS. We note that for the FY 2019 SNF QRP, the standardized resident data elements are already submitted using the same (existing) data submission mechanism.

(3) Schedule for Reporting Standardized Resident Assessment Data Beginning With the FY 2019 SNF QRP

Starting with the FY 2019 SNF QRP, we proposed to apply our current schedule for the reporting of measure data to the reporting of standardized resident assessment data. Under this proposed policy, except for the first program year for which a measure is adopted, SNFs must report data on measures for SNF Medicare admissions that occur during the 12-month calendar year (CY) period that apply to the program year. For the first program year for which a measure is adopted, SNFs are only required to report data on SNF Medicare admissions that occur on or after October 1 and discharged from the SNF up to and including December 31 of the calendar year that applies to that program year. For example, for the FY 2018 SNF QRP, data on measures adopted for earlier program years must be reported for all CY 2016 SNF Medicare admissions that occur on or after October 1, 2016 and discharges that occur on or before December 31, 2016. However, data on newly adopted measures for the FY 2018 SNF QRP program year must only be reported for SNF Medicare admissions and discharges that occur during the last calendar quarter of 2016.

Tables 20 and 21 illustrate this policy using the FY 2019 and FY 2020 SNF QRP as examples.

TABLE 20—SUMMARY ILLUSTRATION OF INITIAL REPORTING CYCLE FOR NEWLY ADOPTED MEASURE AND STANDARDIZED RESIDENT ASSESSMENT DATA REPORTING USING CY Q4 DATA *

Data collection/submission quarterly reporting period *	Data submission quarterly deadlines beginning with FY 2019 SNF QRP *^
Q4: CY 2017 10/1/2017–12/31/2017	CY 2017 Q4 Deadline: May 15, 2018.

* We note that submission of the MDS must also adhere to the SNF PPS deadlines.

^ The term ''FY 2019 SNF QRP'' means the fiscal year for which the SNF QRP requirements applicable to that fiscal year must be met in order for a SNF to receive the full market basket percentage when calculating the payment rates applicable to it for that fiscal year.

TABLE 21—SUMMARY ILLUSTRATION OF CALENDAR YEAR QUARTERLY REPORTING CYCLES FOR MEASURE AND STANDARDIZED RESIDENT ASSESSMENT DATA REPORTING *

Data collection/submission quarterly reporting period *	Data submission quarterly deadlines beginning with FY 2020 SNF QRP *^
Q1: CY 2018 1/1/2018–3/31/2018	CY 2018 Q1 Deadline: August 15, 2018.
Q2: CY 2018 4/1/2018–6/30/2018	CY 2018 Q2 Deadline: November 15, 2018.
Q3: CY 2018 7/1/2018–9/30/2018	CY 2018 Q3 Deadline: February 15, 2019.
Q4: CY 2018 10/1/2018–12/31/2018	CY 2018 Q4 Deadline: May 15, 2019.

* We note that submission of the MDS must also adhere to the SNF PPS deadlines.

^ The term ''FY 2020 SNF QRP'' means the fiscal year for which the SNF QRP requirements applicable to that fiscal year must be met in order for a SNF to receive the full market basket percentage when calculating the payment rates applicable to it for that fiscal year.

In the FY 2018 SNF PPS proposed rule (82 FR 21076 through 21077), we proposed that for the SNF QRP starting with the 2019 SNF QRP, we would apply our current schedule for the reporting of measure data to the reporting of standardized resident assessment data. Specifically, we proposed to apply to the submission of standardized resident assessment data our policy that except for the first program year for which a measure is adopted, SNFs must report data on measures for SNF Medicare admissions that occur during the 12 month calendar year period that apply to the program year and that for the first program year for which a measure is adopted, SNFs are only required to report data on SNF Medicare admissions that occur on or after October 1 and are discharged from the SNF up to and including December 31 of the calendar year that applies to the program year. We sought comment on our proposal to extend our current policy governing the schedule for reporting the quality measure data to the reporting of standardized resident assessment data beginning with the FY 2019 SNF QRP. A discussion of these comments, along with our responses, appears below.

Comment: Commenters supported our proposal to adopt the same data reporting schedule for both standardized resident assessment data and SNF QRP measure data as this creates consistency in reporting. Another commenter added that we should allow facilities to become familiar with the assessment and coding requirements associated with the new standardized resident assessment data elements for a period of time before quality measure reporting begins.

Response: We appreciate commenters' support to extend this policy to the standardized resident assessment data submitted under the SNF QRP. We agree that comprehensive training is needed to ensure accurate data collection and to ensure successful reporting on new measures that are constructed using the new data. As with the data collection required on new assessment data collection in the past, we will provide training sessions, training manuals, webinars, open door forums, help desk support, and a Web site that hosts training information and will continue to provide the training providers may need to understand item concepts and coding instructions.

Comment: In light of the additional data elements being proposed for the MDS, one commenter recommended that the reporting data for the purposes of quality measures for the SNF QRP not begin at the same time as new items are added to the MDS, and requested at least a 3-month time frame of data collection with the new items before the data is collected for use in a quality measure.

Response: We interpret the comment to mean that given the new data elements and need for SNFs to become familiar with the coding of the new standardized resident assessment data elements, the commenter believes that we should not use the first three months of data in the calculation of the measures to be publicly reported. We acknowledge that SNFs may need time to transition to new data reporting requirements. As discussed previously, data collection on new measures that are calculated using resident assessment data begins using a schedule that starts on October 1 of a given year, we anticipate using the subsequent calendar year of data for public reporting.

Final Decision: After careful consideration of the public comments, we are finalizing our proposal to extend our current policy governing the schedule for reporting quality measure data to the standardized resident assessment data elements beginning with the FY 2019 SNF QRP.

(4) Schedule for Reporting the Quality Measures Beginning with the FY 2020 SNF QRP

As discussed in section III.D.2.g. of this final rule, we are finalizing the adoption of five quality measures beginning with the FY 2020 SNF QRP: (1) Changes in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury; (2) Application of IRF Functional Outcome Measure: Change in Self-Care for Medical Rehabilitation Patients (NQF #2633); (3) Application of IRF Functional Outcome Measure: Change in Mobility Score for Medical Rehabilitation Patients (NQF #2634); (4) Application of IRF Functional Outcome Measure: Discharge Self-Care Score for Medical Rehabilitation Patients (NQF #2635); (5) and Application of IRF Functional Outcome Measure: Discharge Mobility Score for Medical Rehabilitation Patients (NQF #2636). In the FY 2018 SNF PPS proposed rule (82 FR 21077) we proposed that SNFs would report data on these measures using the MDS that is submitted through the QIES ASAP system. For the FY 2020 SNF QRP, SNFs would be required to report these data for admissions as well as discharges that occur between October 1, 2018 and December 31, 2018. More information on SNF reporting using the QIES ASAP system is located at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/NursingHomeQualityInits/index.html?redirect=/NursingHomeQualityInits/30_NHQIMDS30TechnicalInformation.asp#TopOfPage.* Starting in CY 2019, SNFs would be required to submit data for the entire calendar year beginning with the FY 2021 SNF QRP.

We sought public comment on this proposal. A discussion of these comments, along with our responses, appears below.

Comment: Two commenters supported our proposal that SNFs report admission and discharge data for the five quality measures beginning with the FY 2020 SNF QRP using the QIES ASAP system.

Response: We thank the commenters for their support.

Final Decision: We are finalizing our policy as proposed for the Schedule for Reporting the Quality Measures Beginning with the FY 2020 SNF QRP.

(5) Input Sought on Data Reporting Related to Assessment Based Measures

Through various means of public input, including that through previous rules (FY 2016 SNF PPS final rule, 80 FR 46415), public comment on measures, and the MAP, we received input suggesting that we expand the quality measures to include all residents and patients regardless of payer status so as to ensure representation of the quality of the services provided on the population as a whole, rather than a subset limited to Medicare. While we appreciate that many SNF residents are also Medicare beneficiaries, we agree that collecting quality data on all residents in the SNF setting supports our mission to ensure quality care for all individuals, including Medicare beneficiaries. We also agree that collecting data on all patients provides the most robust and accurate reflection of quality in the SNF setting. Accurate representation of quality provided in SNFs is best conveyed using data on all SNF residents, regardless of payer. We also appreciate that collecting quality data on all SNF residents regardless of payer source may create additional burden. However, we also note that the effort to separate out SNF residents covered by other non-FFS Medicare payers could have clinical and work flow implications with an associated burden, and we further appreciate that it is common practice for SNFs to collect MDS data on all residents regardless of payer source. Additionally, we note that data collected through MDS for Medicare beneficiaries should match that beneficiary's claims data in certain key respects (for example, diagnoses and procedures); this makes it easier for us to evaluate the accuracy of

reporting in the MDS, such as by comparing diagnoses at hospital discharge to diagnoses at the follow-on SNF admission. However, we would not have access to such claims data for non-Medicare beneficiaries. Thus, we sought input on whether we should require quality data reporting on all SNF residents, regardless of payer, where feasible—noting that Part A claims data are limited to only Medicare beneficiaries.

We sought comments on this topic. A discussion of these comments, along with our responses, appears below.

Comment: We received overwhelming support from commenters including MedPAC and others for the expansion of quality measures to include all residents regardless of payer. Several commenters as well as MedPAC expressed the benefit of enabling comparisons between FFS beneficiaries and other users (including beneficiaries enrolled in Medicare Advantage), expressing that such data would serve to better inform beneficiaries on the broader quality of the entire facility, especially those who are or will become long-term care residents of the same facility. MedPAC also highlighted that while the data collection activity incurs some cost, some providers currently assess all residents routinely. Some commenters conveyed that data collection on all payers is more feasible than having to select only Medicare populations. Several commenters noted that it is advantageous for facilities to focus on quality outcomes for all residents regardless of payer, and several commenters noted that having information on rates for all residents regardless of payor allows providers to utilize these measures in system-based quality improvement initiatives.

One commenter noted a preference for using claims-based data and urged that claims-based SNF QRP measures be re-specified to allow for this inclusion. Another commenter highlighted the value in using readily available MDS assessment-based data to better represent facility performance on measures previously reported using Medicare Part A claims data only.

Response: We acknowledge support for this policy from MedPAC and other commenters. We agree that having such information from all payers adds value to data comparisons, allows enhanced use of assessment data already being collected on all residents, and further supports system-wide quality improvement goals.

(l) Application of the SNF QRP Data Completion Thresholds to the Submission of Standardized Resident Assessment Data Beginning with the FY 2019 SNF QRP

We have received questions surrounding the data completion policy we adopted beginning with the FY 2018 program year, specifically with respect to how that policy applies to patients who reside in the SNF for part of an applicable period, for example, a patient who is admitted to a SNF during one reporting period but discharged in another, or a patient who is assessed upon admission using one version of the MDS but assessed at discharge using another version. We previously finalized in the FY 2016 SNF PPS final rule (80 FR 46458) that SNFs must report all of the data necessary to calculate the measures that apply to that program year on at least 80 percent of the MDS assessments that they submit. The term ''measures'' refers to quality measures, resource use, and other measures. We also stated, in response to a comment, that we would consider data to have been satisfactorily submitted for a program year if the SNF reported all of the data necessary to calculate the measures if the data actually can be used for purposes of such calculations (as opposed to, for example, the use of a dash [-]).

Some stakeholders interpreted our requirement that data elements be necessary to calculate the measures to mean that if a patient is assessed, for example, using one version of the MDS at admission and another version of the MDS at discharge, the two assessments are included in the pool of assessments used to determine data completion only if the data elements at admission and discharge can be used to calculate the measures. Our intention, however, was not to exclude assessments on this basis. Rather, our intention was solely to clarify that for purposes of determining whether a SNF has met the data completion threshold, we would only look at the completeness of the data elements in the MDS for which reporting is required under the SNF QRP.

To clarify our intended policy, in the FY 2018 SNF PPS proposed rule (82 FR 21077 through 21078), we proposed that for the purposes of determining whether a SNF has met the data completion threshold, we would consider whether the SNF has reported all of the required data elements applicable to the program year on at least 80 percent of the MDS assessments that they submit for that program year. For example, if a resident is admitted on December 20, 2017 but discharged on January 10, 2018: (1) The resident's 5-Day PPS assessment would be used to determine whether the SNF met the data completion threshold for the 2017 reporting period (and associated program year), and (2) the discharge assessment would be used to determine whether the SNF met the data completion threshold for the 2018 reporting period (and associated program year). We also clarified in the FY 2018 SNF PPS proposed rule (82 FR 21078) that some assessment data will not invoke a response; in those circumstances, data are not ''missing'' or incomplete. For example, in the case of a resident who does not have any of the medical conditions in a check all that apply listing, the absence of a response indicates that the condition is not present, and it would be incorrect to consider the absence of such data as missing in a threshold determination.

We also proposed to apply this policy to the submission of standardized resident assessment data, and to codify it at § 413.360(b) of our regulations. We sought comment on these proposals. A discussion of these comments, along with our responses, appears below.

Comment: We received a comment noting the usefulness of a document we published indicating which data we would be using to determine compliance by SNFs beginning with the FY 2018 SNF QRP. The commenter also requested that we continue providing that resource. The commenter also acknowledged our clarification of which MDS assessments are included in compliance determinations when the resident admission occurs in one reporting period for the SNF QRP, while their discharge occurs in a subsequent reporting period. The commenter further acknowledged our clarification that an MDS item will not be considered as missing data in the circumstances when no response is necessary.

Another commenter requested additional explanation and examples regarding how the threshold compliance calculation is applied. One commenter suggested that the 80 percent data completion threshold finalized in the SNF PPS FY 2016 final rule is set too low and requested that, for the FY 2018 payment determination year and beyond, the data completion threshold be increased to at least ninety percent. We also received a comment suggesting that requiring that SNFs submit data on 100% of all items necessary to calculate quality measures and all additional standardized resident assessment data elements is set too high. They also expressed that the tracking of dash use, which is what is used to determine compliance, is burdensome. Another

commenter suggested that we omit the first quarter of required data reporting in our determination of compliance given the newness of the reporting. They further expressed that for FY 2018 SNF QRP, the Review and Correct reports that were proved were unavailable for the SNFs to help them identify if they were successful in meeting the compliance threshold.

One commenter did not support the codification of this proposal in our regulations with respect to the FY 2019 SNF QRP, and requested that we first review the results of the initial implementation of this policy and propose such codification in the future.

Response: We appreciate the commenter's support of the materials we provided to help SNFs identify the required MDS data elements for accurate submission in order to meet the requirements of the SNF QRP. We have published the document, *Technical Specifications for Reporting Assessment-Based Measures for FY2018,* which identifies item completion specifications for calculation of missing data rates on our Web site 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* and intend to update this resource document as suggested.

We do not believe that the Review and Correct Reports would be an appropriate mechanism for informing SNFs whether they have complied with our data completion threshold. This report is intended to provide SNFs information related to their overall quality measure calculations. It will not provide SNFs with the discrete, data element level information on what response was coded for every resident assessment data element. We refer to the CMS SNF QRP Training Web site for detailed information on the Review and Correct Reports: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/NursingHomeQualityInits/Skilled-Nursing-Facility-Quality-Reporting-Program/SNF-Quality-Reporting-Program-Training.html.*

Although the Review and Correct Reports do not enable SNFs to track the coding of dashes which is what can lead to non-compliance, we provide other reports via the Certification and Survey Provider Enhanced Reports Reporting (CASPER) System which SNFs can use to track their dash use in the assessment data they have submitted and other submission information. These reports include: Submitter Validation Reports, Facility Final Validation Reports, Error Detail by Facility Reports, Activity or Submission Activity Reports and Assessment Print Reports. We are also looking into other mechanisms and reports that would serve to further assist SNFs in easily identifying their data completion thresholds.

To illustrate an example as requested, if a provider submitted 100 records in a reporting period and 80% of those records had all of the standardized resident assessment data elements that we require and the data necessary to calculate the measures used in the SNF QRP, the SNF would meet our compliance determination.

We currently believe that the completion of all of the required data elements on at least 80 percent of all required assessments is a fair criterion for a new program and is consistent with other post-acute care programs. Regarding the suggestion that we not consider the initial quarter of data reporting by SNFs on new data that is required, we have analyzed the first quarter of data reporting and found that most SNFs were successful in their data submission. We appreciate that SNFs seek to track their compliance rates and the burden that may be associated with their tracking of such data submission. However, we believe that ensuring the submission of accurate data is an inherent responsibility of the SNF. We note that the use of dashes, which is what can lead to a determination of non-compliance, should be rare in that the assessment data collected is required and the expectation is that SNFs perform these assessments on their residents for not only data reporting purposes for the SNF QRP, but also for other purposes as well. As has been noted, overall dash use by SNFs is already low. That said, the reports we provide can assist in a SNF's tracking of their dash rates and we will evaluate other types of reports that can assist.

Final Decision: We are finalizing our proposal to apply the threshold levels as proposed, to extend this policy to the submission of standardized resident assessment data, and to codify the requirement at § 413.360(b) of our regulations.

m. SNF QRP Data Validation Requirements

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.

n. SNF QRP Submission Exception and Extension Requirements

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 SNF QRP. We did not propose any changes to the SNF QRP requirements that we adopted in these final rules. However, in the FY 2018 SNF PPS proposed rule (82 FR 21078) we proposed to codify the SNF QRP Submission Exception and Extension Requirements at new § 413.360(c).

We remind readers that, in the FY 2016 SNF PPS final rule (80 FR 46459 through 46460) we stated that SNF's must request an exception or extension by submitting a written request along with all supporting documentation to CMS via email to the SNF Exception and Extension mailbox at *SNFQRPReconsiderations@cms.hhs.gov.* We further stated that exception or extension requests sent to CMS through any other channel would not be considered as a valid request for an exception or extension from the SNF QRP's reporting requirements for any payment determination. To be considered, a request for an exception or extension must contain all of the requirements as outlined on our Web site at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/NursingHomeQualityInits/Skilled-Nursing-Facility-Quality-Reporting-Program/SNF-QR-Reconsideration-and-Exception-and-Extension.html.* We sought public comments on our proposal to codify the SNF QRP submission exception and extension requirements. A discussion of these comments, along with our responses, appears below.

Comment: A few commenters did not support codification of the SNF QRP Submission Exception and Extension Requirements until one SNF QRP program year has been completed.

Response: Our proposal to codify existing policy in our regulations was technical in nature and would have no effect on its existing applicability and enforceability. To the extent that the commenter was asking us to delay the effective date of this policy, we did not propose such a delay, and we believe that SNFs will benefit from having this process available to them in the event that they experience an extraordinary circumstance during the FY 2018 program year.

Final Decision: After considering the comments we received, we are codifying the SNF QRP submission exception and extension requirements at § 413.360(c) of our regulations.

o. SNF QRP Submission Reconsideration and Appeals Procedures

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 beginning with the FY 2018 SNF QRP. We did not propose any changes to these procedures in the FY 2018 SNF PPS proposed rule (82 FR 21078). However, we proposed to codify the SNF QRP Reconsideration and Appeals procedures at new § 413.360(d). Under these procedures, a SNF must follow a defined process to file a request for reconsideration if it believes that a finding of noncompliance with the reporting requirements for the applicable fiscal year is erroneous, and the SNF can file a request for reconsideration only after it has been found to be noncompliant. To be considered, a request for a reconsideration must contain all of the elements outlined on our Web site at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/NursingHomeQualityInits/Skilled-Nursing-Facility-Quality-Reporting-Program/SNF-QR-Reconsideration-and-Exception-and-Extension.html.* We stated that we would not review any reconsideration request that is not accompanied by the necessary documentation and evidence, and that the request should be emailed to CMS at the following email address: *SNFQRPReconsiderations@cms.hhs.gov.* We further stated that reconsideration requests sent to CMS through any other channel would not be considered.

We sought public comments on our proposal to codify the SNF QRP reconsideration and appeals procedures. A discussion of these comments, along with our responses, appears below.

Comment: Several commenters did not support the codification of SNF QRP Submission Reconsideration and Appeals Procedures until at least the FY 2018 SNF QRP program year has been completed.

Response: Our proposal to codify existing policy in our regulations was technical in nature and would have no effect on its existing applicability and enforceability. To the extent that the commenter was asking us to delay the effective date of this policy, we did not propose such a delay, and we believe that SNFs will benefit from having this process available to them in the event that they wish to seek reconsideration during the FY 2018 program year.

Final Decision: After considering the comments, we are finalizing our decision to codify the SNF QRP submission reconsideration and appeals requirements at new § 413.360(d) of our regulations.

p. Policies Regarding Public Display of Measure Data for the SNF QRP

Section 1899B(g) of the Act requires the Secretary to establish procedures for the public reporting of SNFs' performance, including the performance of individual SNFs, on the quality measures specified under section (c)(1) and resource use and other measures specified under section (d)(1) of the Act (collectively, IMPACT Act measures) beginning not later than 2 years after the specified application date under section 1899B(a)(2)(E) of the Act. This is consistent with the process applied under section 1886(b)(3)(B)(viii)(VII) of the Act, which refers to the public display and review requirements for the Hospital Inpatient Quality Reporting (IQR) Program. For a more detailed discussion about the provider's confidential review process prior to public display of measures, we refer readers to the FY 2017 SNF PPS final rule (81 FR 52045 through 52048).

In the FY 2018 SNF PPS proposed rule, pending the availability of data, we proposed to publicly report data in CY 2018 for the following 3 assessment-based measures: (1) Application of Percent of Long-Term Care Hospital (LTCH) Patients With an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function (NQF #2631); (2) Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (NQF #0678); and (3) Application of Percent of Residents Experiencing One or More Falls with Major Injury (NQF #0674). Data collection for these 3 assessment-based measures began on October 1, 2016. We proposed to display data for the assessment-based measures based on rolling quarters of data, and we would initially use discharges from January 1, 2016 through December 31, 2016.

In addition, we proposed to publicly report 3 claims-based measures for: (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.

These measures were adopted for the SNF QRP in the FY 2017 SNF PPS rule to be based on data from one calendar year. As previously adopted in the FY 2017 SNF PPS final rule (81 FR 52045 through 52047), confidential feedback reports for these 3 claims-based measures will be based on data collected for discharges beginning January 1, 2016 through December 31, 2016. However, our current proposal revises the dates for public reporting and we proposed to transition from calendar year to fiscal year to make these measure data publicly available by October 2018.

For the Medicare Spending Per Beneficiary-PAC SNF QRP and Discharge to Community-PAC SNF QRP measures, we proposed public reporting beginning in calendar year 2018 based on data collected from discharges beginning October 1, 2016, through September 30, 2017 and rates will be displayed based on one fiscal year of data. For the Potentially Preventable 30-day Post-Discharge Readmission Measure for SNF QRP, we also proposed to increase the years of data used to calculate this measure from one year to 2 years and to update the associated reporting dates. These proposed revisions to the Potentially Preventable 30-Day Post-Discharge Readmission Measure for SNF QRP will result in the data being publicly reported with discharges beginning October 1, 2015, through September 30, 2017 and rates will be displayed based on two consecutive fiscal years of data.

Also, we proposed to discontinue the public display of data on the assessment-based measure ''Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short Stay) (NQF #0678)'' and to replace it with a modified version of the measure entitled ''Changes in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury'' from the SNF QRP by October 2020.

For the assessment-based measures, Application of Percent of Long-Term Care Hospital (LTCH) Patients With an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function (NQF #2631); Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (NQF #0678); and Application of Percent of Residents Experiencing One or More Falls with Major Injury (NQF #0674), to ensure the statistical reliability of the measures, we proposed to assign SNFs with fewer than 20 eligible cases during a performance period to a separate category: ''The number of cases/resident stays is too small to report''. If a SNF had fewer than 20 eligible cases, then the SNF's performance would not be publicly reported for the measure for that performance period.

For the claims-based measures Medicare Spending Per Beneficiary-PAC SNF QRP; Discharge to Community-PAC SNF QRP; and Potentially Preventable 30-Day Post-Discharge Readmission Measure for SNF QRP, we proposed to assign SNFs with fewer than 25 eligible cases during a performance period to a separate category: ''The number of cases/resident stays is too small to report,'' to ensure the statistical reliability of the measures. If a SNF had fewer than 25 eligible cases, the SNF's performance would not be publicly reported for the measure for that performance period. For Medicare Spending Per Beneficiary-PAC SNF QRP we proposed to assign SNFs with fewer than 20 eligible cases during a performance period to a separate category: ''The number of cases/resident stays is too small to report'' to ensure the statistical reliability of the measure. If a SNF has fewer than 20 eligible cases, the SNF's performance would not be publicly reported for the measure for that performance period.

TABLE 22—SUMMARY OF PROPOSED MEASURES FOR CY 2018 PUBLIC DISPLAY

Proposed Measures:
Percent of Residents or Patients with Pressure Ulcers that Are New or Worsened (Short Stay) (NQF #0678).
Application of Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay) (NQF #0674).
Application of Percent of Long-Term Care Hospital (LTCH) Patients With an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function (NQF #2631).
Potentially Preventable 30-Day Post-Discharge Readmission Measure for SNF QRP.
Discharge to Community—(PAC) SNF QRP.
Medicare Spending Per Beneficiary (PAC) SNF QRP.

We invited public comment on the proposal for the public display of these three assessment-based measures and three claims-based measures, and the replacement of ''Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short Stay) (NQF #0678)'' with a modified version of the measure, ''Changes in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury'' described above. A discussion of these comments, along with our responses, appears below.

Comment: A commenter requested that we consider aligning the public reporting periods and provider deadlines across PAC settings and other CMS programs.

Response: We are working to achieve alignment where possible. For example, with respect to the following 3 assessment-based measures: (1) Application of Percent of Long-Term Care Hospital (LTCH) Patients With an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function (NQF #2631); (2) Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (NQF #0678); and (3) Application of Percent of Residents Experiencing One or More Falls with Major Injury (NQF #0674), we intend to initially report data using discharges from January 1, 2017 through December 31, 2017 for the public display of data, which aligns with the IRF and LTCH QRPs.

Comment: A commenter supported the proposed minimum denominator requirements for public display.

Response: We appreciate the commenter's support.

Comment: A few commenters supported the public display of assessment-based measures based on rolling quarters since it reflects more recent SNF quality performance.

Response: We appreciate the commenters' support.

Final Decision: After consideration of the public comments we received, we are finalizing that we intend to begin publicly reporting in 2018 the following assessment-based measures based on the availability of data: (1) ''Application of Percent of Long-Term Care Hospital (LTCH) Patients With an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function (NQF #2631); (2) Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (NQF #0678); and (3) Application of Percent of Residents Experiencing One or More Falls with Major Injury (NQF #0674), as well as the following claims-based measures: (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. In addition, we will discontinue the public reporting of data on the assessment-based measure: ''Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short Stay) (NQF #0678)'' by October 2020.

q. Mechanism for Providing Confidential Feedback Reports to SNFs

Section 1899B(f) of the Act requires the Secretary to provide confidential feedback reports to PAC providers on their performance on the measures specified under subsections (c)(1) and (d)(1) of section 1899B of the Act, beginning 1 year after the specified application date that applies to such measures and PAC providers. In the FY 2017 SNF PPS final rule (81 FR 52046 through 52048), we finalized processes to provide SNFs the opportunity to review their data and information using confidential feedback reports that will enable SNFs to review their performance on the measures required under the SNF QRP. Information on how to obtain these and other reports available to the SNF QRP can be found at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/NursingHomeQualityInits/Skilled-Nursing-Facility-Quality-Reporting-Program/SNF-Quality-Reporting-Program-Spotlights-and-Announcements.html.* We did not propose any changes to this policy but received comments, which are discussed below.

Comment: A few commenters requested more granular resident-specific data in the reports.

Response: Resident level data will be available in the CASPER QM reports.

Comment: A commenter suggested that we provide confidential feedback reports to SNFs prior to the time that we publicly display their quality measure data.

Response: Before publicly displaying measure scores, providers have several opportunities to review their facility- and resident-level data to ensure the accuracy of quality measure scores. Two separate confidential feedback reports will be provided, in addition to Review and Correct reports, for providers to review their single quarter and aggregate quality measure scores, respectively. The confidential feedback reports are the QM facility- and resident-level reports that will be available to providers beginning in fall 2017, which is prior to public display, and contain quality measure information for a single reporting period. The facility-level QM reports will provide information such as the numerator, denominator, facility

observed percent, facility adjusted percent, and national average. The resident-level QM reports will contain individual resident data and provide information related to which residents were included in the quality measures.

The Review and Correct reports, currently available to SNFs, provide aggregate performance for up to the past four full quarters as the data are available. The reports contain information on assessment based measures performance at the facility-level and observed rates. The reports also display data correction deadlines and whether the data correction period is open or closed. Please refer to the SNF QRP Web site for information from the training on the Review and Correct reports: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/NursingHomeQualityInits/Skilled-Nursing-Facility-Quality-Reporting-Program/SNF-Quality-Reporting-Program-Training.html.*

Finally, the Provider Preview reports will be available beginning in the summer of 2018. Provider Preview reports are available about 5 months after the end of each reporting period. They contain facility-level quality measure data results and will contain information such as the numerator, denominator, facility observed percent, facility adjusted percent, and national average. Providers will have 30 days upon receiving the Provider Preview reports via their CASPER system folders to review their data. We note at that point in time providers are no longer able to correct the underlying data in these reports. At this point, the data correction period has ended so providers are not able to correct the underlying data in these reports.

3. Skilled Nursing Facility Value-Based Purchasing Program (SNF VBP)

a. Background

Section 215 of the Protecting Access to Medicare Act of 2014 (PAMA) (Pub. L. 113–93) authorized the SNF VBP Program (the ''Program'') by adding sections 1888(g) and (h) to the Act. As a prerequisite to implementing the SNF VBP Program, in the FY 2016 SNF PPS final rule (80 FR 46409 through 46426) we adopted an all-cause, all-condition hospital readmission measure, as required by section 1888(g)(1) of the Act. In the FY 2017 SNF PPS final rule (81 FR 51986 through 52009), we adopted an all-condition, risk-adjusted potentially preventable hospital readmission measure for SNFs, as required by section 1888(g)(2) of the Act. In this final rule, we are finalizing proposals related to the Program's implementation.

Section 1888(h)(1)(B) of the Act requires that the SNF VBP Program 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 towards transforming how care is paid for, moving increasingly towards 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 also refer readers to the FY 2017 SNF PPS final rule (81 FR 51986 through 52009) for discussion of the policies that we adopted related to the potentially preventable hospital readmission measure, scoring, and other topics.

In this rule, we are finalizing requirements for the SNF VBP Program, as well as codifying some of those requirements at § 413.338, including certain definitions, the process for making value-based incentive payments, and limitations on review.

We received several general comments on the SNF VBP Program. We note that we did not receive any comments specific to the proposed regulation text. A discussion of the general comments that we received, along with our responses, appears below.

Comment: One commenter urged us to seek the statutory authority to broaden the scope of the SNF VBP Program to include other post-acute care outcome measures beyond measures of readmissions.

Response: We thank the commenter for this suggestion.

Comment: One commenter suggested that we authorize the inclusion of certified peer specialists in value-based, patient-centered treatment, as well as transition teams assigned to nursing home patients with mental illness or substance use disorders who might benefit in recovery from a return to community-based services. The commenter stated that peer support specialists' work could result in savings to the Medicare Program due to reduced rehospitalizations and from reduced medical expenditures for recurring medical conditions.

Response: We appreciate the comment. We will consider whether peer support specialists could play a role providing technical assistance to SNFs to help them reduce avoidable hospital readmissions through our collaboration with the CMS Quality Innovation and Improvement Network.

Comment: One commenter suggested that we analyze the New York State Nursing Home Quality Initiative, which the commenter stated incorporates quality, compliance and efficiency with a focus on potentially avoidable hospitalizations. While the initiative is limited to long-stay Medicaid patients, the commenter stated that it presents several important lessons for the SNF VBP Program. The commenter specifically pointed to the need to structure measures narrowly for participating facilities, regional adjustments, and detailed information that the commenter believes must be provided to participating facilities. The commenter also stated that potentially avoidable hospitalizations are the most important factor, and that incentive payments must be large enough and close enough to the performance period to maximize improvement.

Response: The New York State Nursing Home Quality Initiative ''is an annual quality and performance evaluation project to improve the quality of care for residents in Medicaid-certified nursing facilities across New York State.'' [49] The initiative scores Medicaid-certified nursing facilities in the state on previous performance and awards up to 100 points for performance on measures of quality, compliance, and efficiency. The initiative also incorporates deficiencies cited during the health inspection survey process and creates an overall score for each facility that forms the basis for a quintile ranking. We appreciate the commenter's suggestion that we consider the New York initiative's results and lessons and we agree that it may be instructive for our continuing SNF VBP Program development. As the commenter noted, its basis in long-stay Medicaid patients differs somewhat from the SNF VBP Program's focus on shorter-stay Medicare patients. However, as the commenter notes, the initiative provides detailed information to participating facilities, a goal that we believe we are now meeting by providing patient-level information to SNF VBP Program participants. We also believe that the SNF VBP Program is, as the commenter

[49] See *https://www.health.ny.gov/health_care/medicaid/redesign/nursing_home_quality_initiative.*

suggests, narrowly constructed due to its focus on measures of hospital readmissions, and while we have not considered regional adjustments in the SNF VBP Program to date, we will consider if such adjustments are appropriate in the future.

Comment: One commenter questioned whether the SNF VBP Program's statute actually limits the Program to the specified measures of readmissions, or whether other indicators could be included in performance scoring. The commenter suggested that, at a minimum, we should coordinate our approach and goals between SNF VBP, SNF QRP, and the Staffing Data Collection initiative. Another commenter suggested that we consider additional quality measures for the Program, potentially including measures drawn from Nursing Home Compare, the NH VBP demonstration, or the SNF QRP. The commenter also specifically suggested that we measure turnover as a percentage of nursing staff, total CNA hours per patient day, and total licensed nursing hours per patient day. The commenter stated that these measures can be integrated into SNF VBP because the payroll-based journal staffing information collection system has been operational since July 2016. The commenter also stated that several studies have positively correlated a higher staffing level with higher care quality and outcomes, and stated that such metrics will encourage SNFs to invest in their staffs.

Response: We interpret sections 1888(h)(2)(A) and (B) of the Act to only allow us to include in the Program first the readmission measure specified under section 1888(g)(1), and then in its place, the readmission measure specified under section 1888(g)(2) of the Act. We will continue our collaborative effort with the SNF QRP and Nursing Home Compare programs to align our readmission measure to the fullest extent feasible and practicable. Our collaborative focus area across these programs is to improve the quality of care and reduce hospital readmissions.

We thank the commenters for this feedback.

b. Measures

(1) Background

For background on the measures in the SNF VBP Program, we refer readers to the FY 2016 SNF PPS final rule (80 FR 46419), where we finalized the Skilled Nursing Facility 30-Day All-Cause Readmission Measure (SNFRM) (NQF #2510) that we will use for the SNF VBP Program. We also refer readers to the FY 2017 SNF PPS final rule (81 FR 51987 through 51995), where we finalized the Skilled Nursing Facility 30-Day Potentially Preventable Readmission Measure (SNFPPR) that we will use for the SNF VBP Program instead of the SNFRM as soon as practicable.

(2) Request for Comment on Measure Transition

Section 1886(h)(2)(B) of the Act requires us to apply the SNFPPR to the SNF VBP Program instead of the SNFRM ''as soon as practicable.'' We intend to propose a timeline for replacing the SNFRM with the SNFPPR in future rulemaking, after we have had a sufficient opportunity to analyze the potential effects of this replacement on SNFs' measured performance. We believe we must approach the decision about when it is practicable to replace the SNFRM thoughtfully, and we continue to welcome public feedback on when it is practicable to replace the SNFRM with the SNFPPR.

In the FY 2017 SNF PPS final rule (81 FR 51995), we summarized the public comments we received in response to our request for when we should begin to measure SNFs on their performance on the SNFPPR instead of the SNFRM. Commenters' views were mixed; one suggested that we replace the SNFRM immediately, while others requested that we wait until the SNFPPR receives NQF endorsement, or that we allow SNFs to receive and understand their SNFPPR data for at least 1 year prior to beginning to use it. Another commenter suggested that we decline to use the SNFPPR until the measure receives additional support from the Measure Application Partnership and is the subject of additional public comment.

We would like to thank stakeholders for their input on this issue. We believe the first opportunity to replace the SNFRM with the SNFPPR would be the FY 2021 program year, which would give SNFs experience with the SNFRM and other measures of readmissions such as those adopted under the SNF QRP. However, we have not yet determined if it would be practicable to replace the SNFRM at that time. We intend to continue to analyze SNF performance on the SNFPPR in comparison to the SNFRM and assess how the replacement of the SNFRM with the SNFPPR will affect the quality of care provided to Medicare beneficiaries.

In the FY 2018 SNF PPS proposed rule, we sought public comments on when we should replace the SNFRM with the SNFPPR, particularly in light of our proposal (discussed further in this section) to adopt performance and baseline periods based on the federal FY rather than on the calendar year. A discussion of these comments, along with our responses, appears below.

Comment: Several commenters supported transitioning to the SNFPPR beginning with the FY 2021 program year as long as the measure has received NQF endorsement. Commenters stated that the measure's importance to the program necessitates thorough vetting, including NQF endorsement, and agreed that waiting until FY 2021 provides SNFs with the opportunity to gain experience with the SNFRM prior to the measure transition. One commenter requested that we provide a timeline for when the measure will replace the SNFRM.

Response: We appreciate the feedback, and we intend to submit the SNFPPR to NQF for consideration of endorsement as soon as possible. We will address the replacement of the SNFRM with the SNFPPR in future rulemaking.

Comment: One commenter expressed continued concern about the SNFPPR, stating that we should conduct additional testing and analysis of the measure before implementing it in the Program. The commenter specifically requested that we await full endorsement by NQF, and if we intend to proceed with its implementation, that we provide SNFPPR performance information in our quarterly reports to SNFs.

Response: As we noted above, we intend to submit the SNFPPR to NQF for consideration of endorsement as soon as possible. We also intend to provide SNFs with SNFPPR performance information in their quarterly reports prior to future replacement of the SNFRM. We intend to update affected stakeholders on timing in future rulemaking.

Comment: One commenter supported adoption of the SNFPPR and did not have any objection to transitioning the Program to the SNFPPR in FY 2021. The commenter also suggested that we consider including additional measures in the Program to cover other relevant quality improvement topics, such as resource use and functional outcomes.

Response: As we discussed above, we interpret sections 1888(h)(2)(A) and (B) of the Act to only allow us to include in the Program first the readmission measure specified under section 1888(g)(1) of the Act, and then in its place, the readmission measure specified under section 1888(g)(2) of the Act. We intend to provide SNF's with SNFPPR rates prior to the replacement for SNF's to learn more about the measure and incorporate into their

quality improvement and care transitions efforts to reduce readmissions. We also intend to further analyze the SNFPPR prior to replacing the SNFRM for any association with social risk factors, in collaboration with the Assistant Secretary for Planning and Evaluation. We intend to update stakeholders on this analysis in future rulemaking.

Comment: One commenter supported transitioning the Program to the SNFPPR in FY 2021, if not sooner, and requested additional information on why we believe that FY 2021 is the first opportunity to transition the Program from the SNFRM.

Response: As we discussed in the FY 2018 SNF PPS proposed rule (82 FR 21080), we concluded that FY 2021 would be the first opportunity to replace the SNFRM with the SNFPPR because we believe that giving SNFs two Program years' experience with the SNFRM will provide them with valuable experience with measures of readmissions that will be helpful for their quality improvement efforts generally and with their specific efforts to improve their scores under the SNF VBP Program. To expand on that point, we did not believe it would be helpful to SNFs' quality improvement efforts to adopt a quality measure for a single year, then to replace that measure after that 1 year, particularly because the Program is limited by statute to a single measure at a time. We viewed that instability in the Program's quality metrics as undesirable and unnecessary. We are also concerned that transitioning the Program too quickly could prove confusing for SNFs and for affected patients.

We also intend to provide SNFs with their SNFPPR rates prior to the replacement so that they have an opportunity to learn more about the measure and incorporate that information into their quality improvement and care transitions efforts to reduce readmissions. We also intend to further analyze the SNFPPR prior to replacing the SNFRM for any association with social risk factors, in collaboration with the Assistant Secretary for Planning and Evaluation. We intend to update stakeholders on this analysis in future rulemaking.

Comment: One commenter recommended that we transition the Program to the SNFPPR no sooner than FY 2021 to allow sufficient time for SNFs to adjust to the measure's implementation.

Response: We agree that SNFs need time to adjust to transitions under the Program, which is why we sought comment in the FY 2017 SNF PPS proposed rule on this topic and again sought comment in the FY 2018 SNF PPS proposed rule. We will consider the commenter's feedback as we determine when it is practicable to transition the Program to the SNFPPR.

We thank the commenters for this feedback and will take it into consideration in the future. We also received a number of unsolicited comments on the SNF VBP Program measures. The comments, together with our responses, appear below.

Comment: One commenter expressed concern about our use of measures of readmissions in the Program. The commenter was particularly concerned that these measures place non-profit facilities at a disadvantage compared to their for-profit competitors because non-profits take all patients, including high-risk and high-acuity level patients. The commenter also stated that the measures' risk adjustment methodologies do not fully capture the additional effort needed to treat these patients in the SNF setting, such as the risk of patient non-compliance with medical direction after discharge. The commenter requested that we provide additional transparency into claims-based quality measures in order to improve providers' understanding of their calculations and methodologies.

Response: We thank the commenter for this feedback, but we disagree with their concern. As we discussed in the FY 2016 SNF PPS final rule (80 FR 46418), we believe that the risk adjustment model that we have adopted for the SNFRM will ensure that SNFs serving more complex patient populations will not be penalized inadvertently under the Program. As we discussed in the FY 2017 SNF PPS final rule (81 FR 51993), we have also specified the SNF Potentially Preventable Readmissions Measure for the Program, and that measure estimates the risk-standardized rate of unplanned, potentially preventable hospital readmissions for Medicare FFS beneficiaries. The comprehensive claims-based risk-adjustment model that the measure employs 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 continue to believe that the measures' risk adjustment methodologies appropriately adjust for factors beyond SNFs' control. We will carefully monitor the Program's effects on SNFs' measured performance and on care quality, and will work with SNFs to provide as much assistance as possible with their efforts to improve on the Program's measures. For additional information on the SNFRM's calculation and methodology, we refer readers to the SNFRM Technical Report available on our Web site at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/NursingHomeQualityInits/Downloads/SNFRM-Technical-Report-3252015.pdf.* For additional information on the SNFPPR's calculation and methodology, we refer readers to the SNFPPR Technical Report 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.*

Comment: Two commenters suggested that we consider removing readmissions from the measure when they are associated with events unrelated to SNF care, such as car accidents or disease outbreaks.

Response: We note that the SNF VBP Program's statute requires that the measure specified under section 1888(g)(1) of the Act must be an ''all-cause all-condition hospital readmission'' measures, which we specified as the SNFRM (NQF #2510). We previously addressed this issue in detail in the FY 2016 SNF PPS Final Rule (80 FR 46412 through 46413). We explained that the SNFRM has been risk adjusted for case-mix to account for differences in patient populations. The goal of risk adjustment is to account for these differences so that providers who treat sicker or more vulnerable patient populations are not unnecessarily penalized for factors that are outside of their control. Regarding hospitalizations due to other incidents unrelated to SNF care such as car accidents and non-preventable disease outbreaks, we note that these events are random and would not be likely to cluster in certain SNFs over time; thus they would not result in systematic bias in the measure.

Comment: One commenter suggested that we factor the expansion of managed care into our measure development process, noting that many states are rapidly expanding managed care offerings for both Medicare and Medicaid patients. The commenter suggested that we consider consolidating quality measure requirements between Medicare and Medicaid to minimize the burden on participating providers, and suggested that we promote best practices in quality improvement as widely as possible.

Response: The measures that we have adopted for the Program are based on Medicare claims, and are thus restricted to Medicare fee-for-service beneficiaries. We believe that policy to be appropriate given the Program's focus on Medicare fee-for-service payments. From our collaboration with the Quality Innovation and Improvement Networks, we also believe that many of the care transitions and quality improvement strategies used by SNFs are broadly applicable to reduce readmissions for Medicaid and managed-care patients. We will consider methods to monitor managed-care performance in the future, and welcome commenters' input on that topic.

Comment: One commenter urged us to refine and test the SNFPPR further before adopting it for the Program. The commenter was also concerned about our use of differing measures within the same service line, noting that the re-hospitalization measure currently in use in the Nursing Home Five-Star Quality Rating differs from the SNFPPR. The commenter stated that our longer-term goal should be to align the SNF VBP measure with other relevant hospitalization measures such as those used in VBP programs developed under Medicaid waivers.

Response: We thank the commenter for the suggestion. We wish to clarify that we are conducting additional testing on the SNFPPR measure, in preparation to submit that measure to NQF for endorsement consideration. We wish to clarify that the re-hospitalization measure reported on *Nursing Home Compare* is not a measure of potentially preventable readmissions, as required by PAMA. We agree that aligning measures across Programs, when feasible, may reduce provider confusion.

Comment: One commenter discussed the length of the readmission window for both the SNFRM (NQF #2510) and the SNFPPR. The commenter urged us to extend the readmission window to include the entire SNF stay and a set period after discharge from the SNF.

Response: We believe that the length of the readmission windows for the SNFRM and SNFPPR is appropriate because they are harmonized with measures used in the hospital setting. We note also that a longer readmission window, such as 90-days, would make it difficult to ensure that potentially preventable readmissions occurring up to 90 days after prior hospital discharge are attributable to the SNF care received. We refer readers to the FY 2017 SNF PPS Final Rule (81 FR 51993) for additional details concerning the length of the readmission window for SNF VBP Program measures.

We thank commenters for their feedback.

(3) Updates to the Skilled Nursing Facility 30-Day All-Cause Readmission Measure (NQF#2510)

Since finalizing the SNFRM for use in the SNF VBP Program, we have continued to conduct analyses using more recent data, as well as to make some necessary non-substantive measure refinements. Results of this work and all refinements are detailed in a *Technical Report Supplement* that is available on the following CMS Web site at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/Other-VBPs/SNF-VBP.html.*

We did not receive any public comments on this topic.

(4) Accounting for Social Risk Factors in the SNF VBP Program

We understand that social risk factors such as income, education, race and ethnicity, employment, disability, community resources, and social support (certain factors of which are also sometimes referred to as socioeconomic status (SES) factors or socio-demographic status (SDS) factors) play a major role in health. One of our core objectives is to improve beneficiary outcomes including reducing health disparities, and we want to ensure that all beneficiaries, including those with social risk factors, receive high quality care. In addition, we sought to ensure that the quality of care furnished by providers and suppliers is assessed as fairly as possible under our programs while ensuring that beneficiaries have adequate access to excellent care.

We have been reviewing reports prepared by the Office of the Assistant Secretary for Planning and Evaluation (ASPE) [50] and the National Academies of Sciences, Engineering, and Medicine on the issue of accounting for social risk factors in CMS's value-based purchasing and quality reporting programs, and considering options on how to address the issue in these programs. On December 21, 2016, ASPE submitted a Report to Congress on a study it was required to conduct under section 2(d) of the Improving Medicare Post-Acute Care Transformation (IMPACT) Act of 2014. The study analyzed the effects of certain social risk factors in Medicare beneficiaries on quality measures and measures of resource use used in one or more of nine Medicare value- based purchasing programs, including the SNF VBP Program.[51] The report also included considerations for strategies to account for social risk factors in these programs. In a January 10, 2017 report released by The National Academies of Sciences, Engineering, and Medicine, that body provided various potential methods for measuring and accounting for social risk factors, including stratified public reporting.[52]

As noted in the FY 2017 IPPS/LTCH PPS final rule, the NQF has undertaken a 2-year trial period in which certain new measures, measures undergoing maintenance review, and measures endorsed with the condition that they enter the trial period can be assessed to determine whether risk adjustment for selected social risk factors is appropriate for these measures. This trial entails temporarily allowing inclusion of social risk factors in the risk-adjustment approach for these measures. At the conclusion of the trial, NQF will issue recommendations on the future inclusion of social risk factors in risk adjustment for these quality measures, and we will closely review its findings.

The SNF VBP section of ASPE's report examined the relationship between social risk factors and performance on the 30-day SNF readmission measure for beneficiaries in SNFs. Findings indicated that beneficiaries with social risk factors were more likely to be re-hospitalized but that this effect was significantly smaller when the measure's risk adjustment variables were applied (including adjustment for age, gender, and comorbidities), and that the effect of dual enrollment disappeared. In addition, being at a SNF with a high proportion of beneficiaries with social risk factors was associated with an increased likelihood of readmissions, regardless of a beneficiary's social risk factors.

As we continue to consider the analyses and recommendations from these reports and await the results of the NQF trial on risk adjustment for quality measures, we are continuing to work with stakeholders in this process. As we

[50] Office of the Assistant Secretary for Planning and Evaluation. 2016. Report to Congress: Social Risk Factors and Performance Under Medicare's Value-Based Purchasing Programs. Available at *https://aspe.hhs.gov/pdf-report/report-congress-social-risk-factors-and-performance-under-medicares-value-based-purchasing-programs.*

[51] Office of the Assistant Secretary for Planning and Evaluation. 2016. Report to Congress: Social Risk Factors and Performance Under Medicare's Value-Based Purchasing Programs. Available at *https://aspe.hhs.gov/pdf-report/report-congress-social-risk-factors-and-performance-under-medicares-value-based-purchasing-programs.*

[52] National Academies of Sciences, Engineering, and Medicine. 2017. Accounting for social risk factors in Medicare payment. Washington, DC: The National Academies Press.

have previously communicated, we are concerned about holding providers to different standards for the outcomes of their patients with social risk factors because we do not want to mask potential disparities or minimize incentives to improve the outcomes for disadvantaged populations. Keeping this concern in mind, while we sought input on this topic previously, we again sought public comment on whether we should account for social risk factors in the SNF VBP Program, and if so, what method or combination of methods would be most appropriate for accounting for social risk factors. Examples of methods include: Adjustment of the payment adjustment methodology under the SNF VBP Program; adjustment of provider performance scores (for instance, stratifying providers based on the proportion of their patients who are dual eligible); confidential reporting of stratified measure rates to providers; public reporting of stratified measure rates; risk adjustment of measures as appropriate based on data and evidence; and redesigning payment incentives (for instance, rewarding improvement for providers caring for patients with social risk factors or incentivizing providers to achieve health equity). While we consider whether and to what extent we currently have statutory authority to implement one or more of the above-described methods, we sought comments on whether any of these methods should be considered, and if so, which of these methods or combination of methods would best account for social risk factors in the SNF VBP Program.

In addition, we sought public comment on which social risk factors might be most appropriate for stratifying measure scores and/or potential risk adjustment of a particular measure. Examples of social risk factors include, but are not limited to, dual eligibility/low-income subsidy, race and ethnicity, and geographic area of residence. We are seeking comments on which of these factors, including current data sources where this information would be available, could be used alone or in combination, and whether other data should be collected to better capture the effects of social risk. We will take commenters' input into consideration as we continue to assess the appropriateness and feasibility of accounting for social risk factors in the SNF VBP Program. We note that any such changes would be proposed through future notice-and-comment rulemaking.

We look forward to working with stakeholders as we consider the issue of accounting for social risk factors and reducing health disparities in CMS programs. Of note, implementing any of the above methods would be taken into consideration in the context of how this and other CMS programs operate (for example, data submission methods, availability of data, statistical considerations relating to reliability of data calculations, among others), and we also welcome comment on operational considerations. CMS is committed to ensuring that its beneficiaries have access to and receive excellent care, and that the quality of care furnished by providers and suppliers is assessed fairly in CMS programs.

Commenters submitted the following comments related to the proposed rule's discussion of the Accounting for Social Risk Factors in the SNF VBP Program. A discussion of these comments, along with our responses, appears below.

Comment: Many commenters encouraged us to incorporate social risk factors adjustments in various forms, including stratifying providers into peer groups. Commenters stated that we should require measure developers to incorporate SDS data elements testing in risk adjustment models and suggested that we consider adjusting measures for dual-eligible status as well as education level, limited English proficiency, and living alone, among other possible factors. Some commenters suggested that we examine the Program's effects on specialty populations such as children and residents that are ventilator-dependent, patients receiving dialysis, or patients living with HIV/AIDS. Other commenters suggested that we use IMPACT Act measure data to risk-adjust measures and provider performance scores. One commenter suggested that we consider a stratification approach similar to that proposed for the Hospital Readmissions Reduction Program.

Other commenters encouraged us to incorporate into our future policies the findings both from NQF's sociodemographics trial and from ASPE's report. One commenter noted that the ASPE report found that provider-level factors are more powerful predictors of readmissions than beneficiary-level factors, and that high-dual SNFs were among the best performers on the readmission measure examined. The commenter stated that these results alone do not suggest a need for risk adjustment, but suggested again that we examine NQF's results before determining whether or not risk adjustment is appropriate in the Program, and further suggested that incorporating SES variables into the measures' risk-adjustment model could embed health disparities, create biases in reporting, undermine system-based approaches to providing high-quality care, and create care access problems. Another commenter noted that adjusting for social risk factors could negatively affect providers and facilities in regions where social risk factors are higher, but cautioned that adjusting for such factors may increase health disparities by essentially masking them.

One commenter suggested that we consider developing readmission measures or statistical approaches to report quality performance specifically for beneficiaries with social risk factors. The commenter noted that high social risk beneficiaries are substantially more likely to be re-hospitalized, and that beneficiaries at SNFs serving a high proportion of beneficiaries with social risk factors are also more likely to be re-hospitalized. The commenter stated that these findings suggest that the SNFPPR's outcomes could vary significantly due to factors beyond the SNF's control.

Response: We appreciate all the comments and interest in this topic. As we have previously stated, we are concerned about holding providers to different standards for the outcomes of their patients with social risk factors, because we do not want to mask potential disparities or minimize incentives to improve outcomes for disadvantaged populations. We believe that the path forward should incentivize improvements in health outcomes for disadvantaged populations while ensuring that beneficiaries have access to excellent care. We intend to consider all suggestions as we continue to assess each measure and the overall program. We appreciate that some commenters recommended risk adjustment as a strategy to account for social risk factors, while others stated a concern that risk adjustment could minimize incentives and reduce efforts to address disparities for patients with social risk factors. We intend to conduct further analyses on the impact of strategies such as measure-level risk adjustment and stratifying performance scoring to account for social risk factors including the options suggested by commenters. In addition, we appreciate the recommendations from the commenters about consideration of specific social risk factor variables and will work to determine the feasibility of collecting these patient-level variables. As we consider the feasibility of collecting patient-level data and the impact of strategies to account for social risk factors through further analysis, we will continue to evaluate the reporting

burden on providers. Future proposals would be made after further research and continued stakeholder engagement.

We thank commenters for their feedback. We will take it into account in future rulemaking.

c. FY 2020 Performance Standards

We refer readers to the FY 2017 SNF PPS final rule (81 FR 51995 through 51998) for a summary of the statutory provisions governing performance standards under the SNF VBP Program and our finalized performance standards policy, as well as the numerical values for the achievement threshold and benchmark for the FY 2019 program year. We also responded to public comments on these policies in that final rule.

In the proposed rule (82 FR 21081 through 21802), we proposed estimated performance standards for the FY 2020 SNF VBP Program based on the FY 2016 MedPAR files including a 3-month run-out period. We stated our intention to include the final numerical values of the performance standards in the final rule. We have displayed the estimated performance standards' numerical values from the proposed rule in Table 23. As we have done previously, we have inverted the SNFRM rates in Table 23 so that higher values represent better performance.

TABLE 23—ESTIMATED FY 2020 SNF VBP PROGRAM PERFORMANCE STANDARDS

Measure ID	Measure description	Achievement threshold	Benchmark
SNFRM	SNF 30-Day All-Cause Readmission Measure (NQF #2510)	0.80218	0.83721

We sought public comments on these estimated achievement threshold and benchmark values. A discussion of these comments, along with our responses, appears below.

Comment: One commenter supported our performance standards methodology in general. The commenter was concerned, however, that continually rewarding lower readmission rates may not be in the best interests of SNF patients. The commenter suggested that we explore identifying an optimal readmission rate.

Response: Our statistically based benchmark is intended to set an empirically based performance standard of top performing SNFs as an achievable goal for all SNFs during the performance period. We recognize that this benchmark might not be an optimal readmission rate as suggested by the commenter due to performance gaps between current and optimal care, but the intent of the Program's incentives is to encourage SNFs to improve the care they provide. We also caution that establishing a single optimal readmission rate may not be feasible for a nationwide quality program affecting care for millions of Medicare beneficiaries. We intend to carefully monitor the Program's effects on readmission rates and on care quality, and if warranted, will revisit the performance standards methodology in future rulemaking.

In this final rule, we are providing the finalized numerical values of the achievement threshold and the benchmark for the FY 2020 program year. We note that the values have not changed since we published the proposed rule.

Additionally, as discussed further below, we are finalizing baseline and performance periods for the FY 2020 program year based on the federal fiscal year rather than the calendar year as we had finalized for the FY 2019 program year. The numerical values for the achievement threshold and benchmark in Table 24 reflect this final policy by using FY 2016 claims data. As we have done in prior rulemaking, we have inverted the SNFRM rates in Table 24 so that higher values represent better performance.

TABLE 24—FINAL FY 2020 SNF VBP PROGRAM PERFORMANCE STANDARDS

Measure ID	Measure description	Achievement threshold	Benchmark
SNFRM	SNF 30-Day All-Cause Readmission Measure (NQF #2510)	0.80218	0.83721

After consideration of the public comments that we received, we are finalizing the performance standards for the FY 2020 SNF VBP Program as proposed.

d. FY 2020 Performance Period and Baseline Period

(1) Background

We refer readers to the FY 2016 SNF PPS final rule (80 FR 46422) for a discussion of the considerations that we took into account when specifying performance periods for the SNF VBP Program. Based on those considerations, as well as public comments received, we adopted CY 2017 as the performance period for the FY 2019 SNF VBP Program, with a corresponding baseline period of CY 2015.

(2) FY 2020 Policies

As we stated in the proposed rule (82 FR 21082), we continue to believe that a 12-month performance and baseline period are appropriate for the Program, and we are concerned about the operational challenges of linking the 12-month periods to the calendar year. Specifically, the allowance of an approximately 90-day claims run out period following the last date of discharge, coupled with the length of time needed to calculate the measure rates using multiple sources of claims needed for statistical modeling, determine achievement and improvement scores, allow SNFs to review their measure rates, and determine the amount of payment adjustments could risk delay in meeting requirement at section 1888(h)(7) of the Act to notify SNFs of their value-based incentive payment percentages not later than 60 days prior to the fiscal year involved.

We therefore considered what policy options we had to mitigate this risk and ensure that we comply with the statutory deadline to notify SNFs of their payment adjustments under the Program.

We continue to believe that a 12-month performance and baseline period provide a sufficiently reliable and valid data set for the SNF VBP Program. We

also continue to believe that, where possible and practicable, the baseline and performance period should be aligned in length and in months included in the selections. Taking those considerations and beliefs into account, we proposed to adopt FY 2018 (October 1, 2017, through September 30, 2018) as the performance period for the FY 2020 SNF VBP Program, with FY 2016 (October 1, 2015, through September 30, 2016) as the baseline period for purposes of calculating performance standards and measuring improvement. We noted that this proposed policy, would, if finalized, give us an additional 3 months between the conclusion of the performance period and the 60-day notification deadline prescribed by section 1888(h)(7) of the Act to complete the activities described above.

We are aware that making this transition from the calendar year to the FY will result in our measuring SNFs on their performance during Q4 of 2017 (October 1, 2017, through December 31, 2017) for both the FY 2019 program year and the FY 2020 program year. During the FY 2019 program year, that quarter will fall at the end of the finalized performance period (January 1, 2017, through December 31, 2017), while during the FY 2020 program year, that quarter will fall at the beginning of the proposed performance period (October 1, 2017, through September 30, 2018). We believe that, on balance, this overlap in data is more beneficial than the alternative. We considered proposing not to use that quarter of measured performance during the FY 2020 program year, but, as a result, we would be left with fewer than 12 months of data with which to score SNFs under the program. As we have stated, we believe it is important to use 12 months of data to avoid seasonality issues and to assess SNFs fairly. We therefore believe that meeting these operational challenges, in total, outweighs any cost to SNFs associated with including a single quarter's SNFRM data in their SNF performance scores twice.

However, as an alternative, we requested comments on whether or not we should instead consider adopting for the FY 2020 Program a one-time, three-quarter performance period of January 1, 2018, through September 30, 2018, and a one-time, three-quarter baseline period of January 1, 2016 through September 30, 2016 to avoid the overlap in performance period quarters that we describe above. We believe this option could provide us with sufficiently reliable SNFRM data for purposes of the Program's scoring while ensuring that SNFs are not scored on the same quality measure data in successive Program years. However, we noted that the shorter measurement period could result in lower denominator counts and seasonal variations in care, as well as disparate effects of cold weather months on SNFs' care could also create variations in quality measurement, and could potentially disproportionately affect SNFs in different areas of the country. Under this alternative, we would resume a 12-month performance and baseline period beginning with the FY 2021 program year.

We sought public comments on our proposal and alternative. In addition, as we continue considering potential policy changes once we replace the SNFRM with the SNFPPR, we also sought comment on whether we should consider other potential performance and baseline periods for that measure. We specifically sought comments on whether we should attempt to align the SNF VBP Program's performance and baseline periods with other CMS value-based purchasing programs, such as the Hospital VBP Program or Hospital Readmissions Reduction Program, which could mean proposing to adopt performance and baseline periods that run from July 1st to June 30th. A discussion of these comments, along with our responses, appears below.

Comment: Some commenters supported our proposed performance and baseline periods for the FY 2020 Program, acknowledging that the one-quarter overlap may be unavoidable and agreeing with us that a three-quarter performance period would not be appropriate. Commenters also stated that it is not necessary to align the SNF VBP Program's performance periods with other VBP programs.

Response: We thank the commenters for their support and feedback.

Comment: Some commenters expressed concern about the SNF VBP Program's shift from calendar year to fiscal year measurement periods while the SNF QRP has proposed the reverse. Commenters were concerned that this lack of alignment between the two programs could be confusing for providers.

Response: As described above, the SNF VBP Program's shift from calendar year to fiscal year measurement periods is logistically necessary to meet the statutory deadlines for the program. CMS will take all necessary steps to minimize any potential confusion among providers.

Comment: One commenter opposed our proposal to maintain 12-month performance and baseline periods while shifting to fiscal year reporting periods, and stated that we should instead use a one-time three-quarter baseline and performance period for the FY 2020 Program year. Another commenter recommended that we use only 9 months for the performance and baseline periods for FY 2019 and FY 2020, and then beginning with FY 2021, consider aligning the reporting periods to other VBP programs that run from July 1 to June 30 of each year. The commenter noted that making this change would result in a six-month overlap as opposed to the 3-month overlap under the proposal, with the result being that the change would occur over 2 years.

Response: We thank the commenters for this feedback. However, as we described in the proposed rule, we are concerned that a shorter performance period than a 12-month period could result in lower denominator counts and seasonal variations in care, which could disproportionately affect SNFs in different regions of the country. Our analysis of 9 and 12 month SNFRM denominator size reveals that these issues are sufficiently mitigated by the commenters' suggestion, and we continue to believe that a one-quarter overlap in performance periods between FY 2019 and FY 2020 is an acceptable compromise to make this transition to performance and baseline periods centered on the federal fiscal year.

Additionally, we believe that using a full year of claims data to calculate performance on the measures ensures that the variation found among SNF performance is due to real differences in care delivery between SNFs, and not within-facility variation due to issues such as seasonality. Based on our SNFRM denominator analysis, we do not believe that using a 9-month performance period would provide us with sufficiently reliable data for a performance year, and given the Program's focus on a single quality measure, we do not believe scoring insufficiently reliable quality measure data to be a practical policy.

After consideration of the public comments that we have received, we are finalizing the performance and baseline period for the FY 2020 SNF VBP Program as proposed.

e. SNF VBP Performance Scoring

We refer readers to the FY 2017 SNF PPS final rule (81 FR 52000 through 52005) for a detailed discussion of the scoring methodology that we have finalized for the Program, along with responses to public comments on our policies and examples of scoring calculations.

(1) Rounding Clarification for SNF VBP Scoring

In the FY 2017 SNF PPS final rule (81 FR 52001), we adopted formulas for scoring SNFs on achievement and improvement. The final step in these calculations is rounding the scores to the nearest whole number.

As we have continued examining SNFRM data, we have identified a concern related to that rounding step. Specifically, we are concerned that rounding SNF performance scores to the nearest whole number is insufficiently precise for purposes of establishing value-based incentive payments under the Program. Rounding scores in this manner has the effect of producing significant numbers of tie scores, since SNFs have between 0 and 100 points available under the Program, and we estimate that more than 15,000 SNFs will participate in the Program. As discussed further in this section, the exchange function methodology that we proposed to adopt is most easily implemented when we are able to differentiate precisely among SNF performance scores to provide each SNF with a unique value-based incentive payment percentage.

We therefore proposed to change the rounding policy from that previously finalized for SNF VBP Program scoring methodology, and instead to award points to SNFs using the formulas that we adopted in last year's rule by rounding the results to the nearest ten-thousandth of a point. Using significant digits terminology, we proposed to use no more than five significant digits to the right of the decimal point when calculating SNF performance scores and subsequently calculating value-based incentive payments.

We view this policy change as necessary to ensure that the Program scores SNFs as precisely as possible and to ensure that value-based incentive payments reflect SNF performance scores as accurately as possible.

We sought public comments on this proposal. A discussion of these comments, along with our responses, appears below.

Comment: Some commenters supported our proposal to round SNF performance scores to the fifth significant digit, noting that the step is necessary to avoid ties and that it will have only minor financial impacts.

Response: We thank the commenters for their support.

Comment: Several commenters cautioned that we should not implement policy changes merely to ensure more differentiation among providers.

Response: We thank the commenters for their support. We agree with the commenters that we should not implement policy changes solely to ensure more differentiation, but we view this policy as necessary in order to ensure that SNF performance scores are accurate. We will also consider this caution as we adopt policies in future rulemaking.

Comment: One commenter opposed our proposal to round SNF performance scores to the nearest ten-thousandth of a point, stating that scoring in this manner is ''too narrow.'' The commenter recommended instead that we round scores to the nearest tenth of a point.

Response: We thank the commenter for this feedback, but we believe that rounding scores to the nearest tenth of a point would still result in numerous scoring ties due to the estimated 15,000 SNFs that will participate in the Program. We believe that the rounding policy we have proposed ensures that we have sufficient precision to calculate performance scores under the program.

Comment: One commenter suggested that if our proposed change to the rounding policy for SNF performance scores results in SNFs with nearly identical readmission rates receiving materially different VBP payment amounts, we should consider revising the methodology.

Response: We thank the commenter and agree. Our expectation is that the additional precision will not significantly affect SNFs' payment amounts when they have nearly identical SNF performance scores, but we will monitor this issue carefully.

After consideration of the public comments that we have received, we are finalizing that we will round the SNF performance scores to the fifth significant digit.

(2) Policies for Facilities With Zero Readmissions During the Performance Period

In our analyses of historical SNFRM data, we identified a unit imputation issue associated with certain SNFs' measured performance. Specifically, we found that a small number of facilities had zero readmissions during the applicable performance period. An observed readmission rate of zero is a desirable outcome; however, due to risk-adjustment and the statistical approach used to calculate the measure, outlier values are shifted towards the mean, particularly for smaller SNFs. As a result, observed readmission rates of zero result in risk-standardized readmission rates that are greater than zero. Analysis conducted by our measure development contractor revealed that it may be possible—although rare—for SNFs with zero readmissions to receive a negative value-based incentive payment adjustment. We are concerned that assigning a net negative value-based incentive payment to a SNF that achieved zero readmissions during the applicable performance period would not support the Program's goals.

We considered our policy options for SNFs that could be affected by this issue, including excluding SNFs with zero readmissions from the Program entirely to ensure that they are not unduly harmed by being assigned a non-zero RSRR by the measure's finalized methodology. However, because the Program's statute requires us to include all SNFs in the Program, we do not believe we have the authority to exclude any SNFs from the payment withhold and from value-based incentive payments. We also considered proposing to replace SNF performance scores for those SNFs in this situation with the median SNF performance score. But because we must pay SNFs ranked in the lowest 40 percent less than the amount they would otherwise be paid in the absence of the SNF VBP, we do not believe that assigning these SNFs the median performance rate on the applicable measure would necessarily protect them from receiving net negative value-based incentive payments.

We are considering different policy options to ensure that SNFs achieving zero readmissions among their patient populations during the performance period do not receive a negative payment adjustment. We intend to address this topic in future rulemaking, and we request public comments on what accommodations, if any, we should employ to ensure that SNFs meeting our quality goals are not penalized under the Program. We specifically sought comments on the form this potential accommodation should take. A discussion of these comments, along with our responses, appears below.

Comment: Some commenters expressed concerns about the risk adjustment methodology employed to calculate the measures, particularly for SNFs with zero readmissions during the applicable period. Commenters noted that the statistical approach employed by the measures means that SNFs with low volume or zero readmissions during the applicable period could receive a worse risk-standardized readmission rate, which could hide true differences in performance and may dampen SNFs' incentives to improve. Commenters

suggested that we consider expanding the performance periods for SNFs with low volume to mitigate these effects. Other commenters suggested that we consider returning the full 2 percentage points withheld from SNFs' Medicare payments when those SNFs have zero readmissions during the applicable period, provide a rolling average readmission rate, or stratify readmission rates and value-based incentive payments by facility size.

Response: We intend to address this topic in future rulemaking, and will take these suggestions into account at that time.

Comment: One commenter believed that we should develop an exceptions policy for SNFs in special circumstances, and recommended that under this policy, we return affected SNFs' entire payment withhold and not assign public rankings or scores. The commenter recommended that we offer this exception to SNFs based on a small denominator size of fewer than 25 cases rather than zero readmissions. The commenter noted that a small denominator size would likely capture SNFs with zero readmissions and would ensure that low-volume SNFs do not stack at the top of the Program's ranking and harm non-zero denominator facilities' standing.

Response: We thank the commenter for this feedback and will take it into account in future rulemaking.

We thank the commenters for their feedback, and will take it into account in the future.

(3) Request for Comments on Extraordinary Circumstances Exception Policy

In other value-based purchasing programs, such as the Hospital VBP Program (see 78 FR 50704 through 50706), as well as several of our quality reporting programs, we have adopted Extraordinary Circumstances Exceptions policies intended to allow participating facilities to receive administrative relief from program requirements due to natural disasters or other circumstances beyond the facility's control that may affect the facility's ability to provide high-quality health care.

We are considering whether this type of policy would be appropriate for the SNF VBP Program. We intend to address this topic in future rulemaking. We therefore sought public comments on whether we should implement such a policy, and if so, the form the policy should take. If we propose such a policy in the future, our preference would be to align it with the Extraordinary Circumstances Exception policy adopted under our other quality programs. A summary of the public comments that we received, along with our responses, appears below.

Comment: Some commenters stated their belief that we should adopt an Extraordinary Circumstances Exception policy to provide administrative relief to SNFs suffering from circumstances beyond their control, and recommended that we align the policy with the Hospital VBP Program. Other commenters suggested that we consider adopting the same exception process as has been adopted under the SNF QRP.

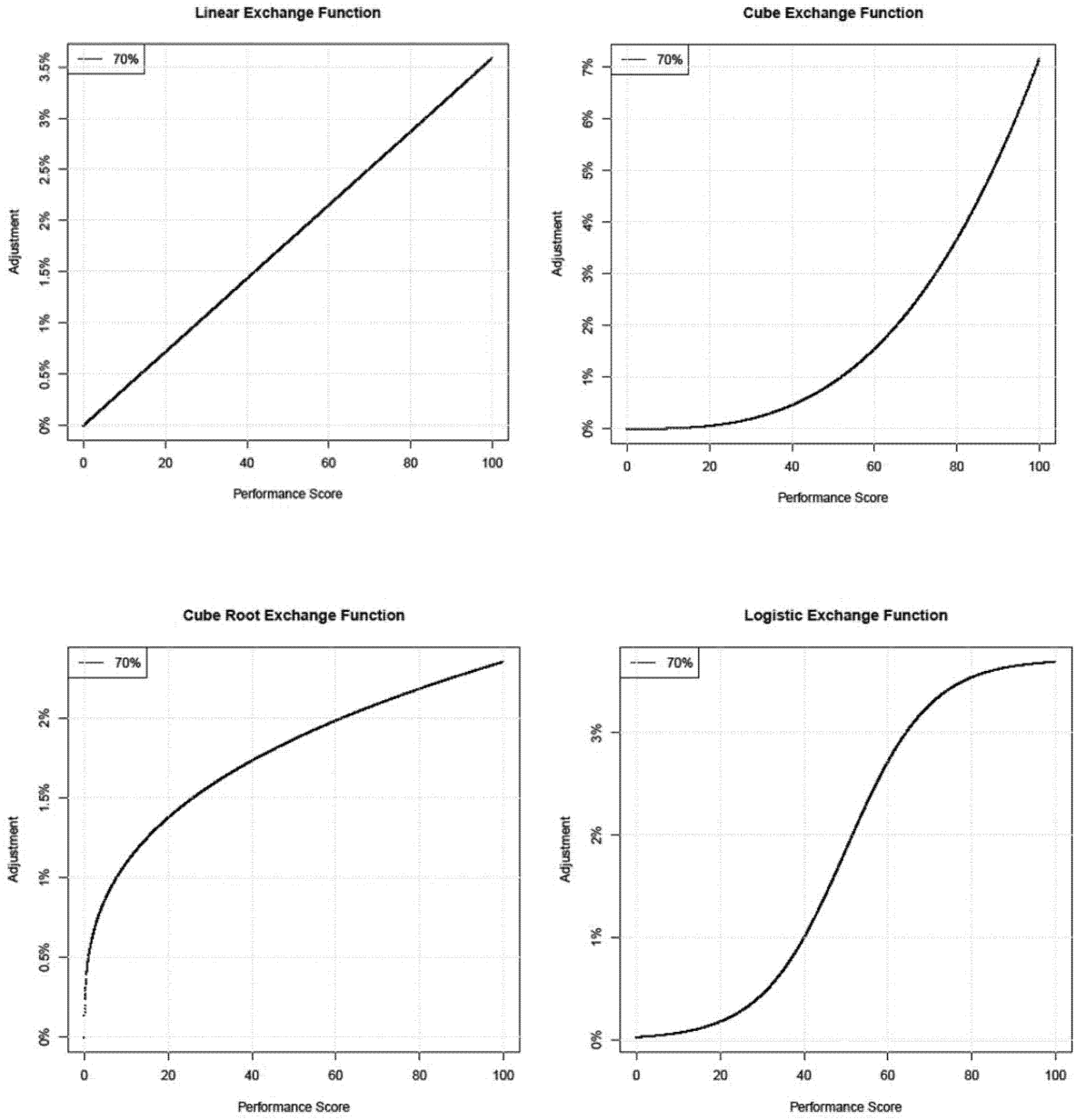
Response: We thank the commenters for their suggestions, and will take it into consideration if we decide to propose an Extraordinary Circumstances Exception policy in future rulemaking.

f. SNF Value-Based Incentive Payments

(1) Exchange Function

We refer readers to the FY 2017 SNF PPS final rule (81 FR 52005 through 52006) for discussion of four possible exchange functions that we considered adopting to translate SNFs' performance scores into value-based incentive payments. We created new graphical representations of the four functions that we have considered in the past—linear, cube, cube root, and logistic—and presented those updated representations in the proposed rule (82 FR 21084). We noted that the actual exchange functions' forms and slopes will vary depending on the distributions of SNFs' performance scores from the FY 2019 performance period, and wished to emphasize that these representations are presented solely for the reader's clarity as we discussed our exchange function policy.

FIGURE 1: SNF VBP Exchange Function Forms That We Considered



We have continued examining historical SNFRM data while considering our policy options for this program. We have attempted to assess how each of the four possible exchange functions that we set out in the FY 2017 SNF PPS final rule, as well as potential variations, would affect SNFs' incentive payments under the Program. We specifically considered the effects of the statutory constraints on the Program's value-based incentive payments and our belief that to create an effective incentive payment program, SNFs' value-based incentive payments must be widely distributed to reward higher performing SNFs through increased payment and to make reduced payments to lower performing SNFs. We also considered our desire to avoid unintended consequences of the Program's incentive payments, particularly since the Program is limited by statute to using a single measure at a time, and our view that an equitable distribution of value-based incentive payments would be most appropriate to ensure that all SNFs, including SNFs serving at-risk populations, could potentially qualify for incentive payments.

In our view, important factors when adopting an exchange function include the number of SNFs that receive more in value-based incentive payments than the number of SNFs for which a reduction is applied to their Medicare payments, as well as the incentive for SNFs to reduce hospital readmissions. We hold this view because we believe that the Program will be most effective at encouraging SNFs to improve the quality of care that they provide to Medicare beneficiaries if SNFs have the opportunity to earn incentives, rather than simply avoid penalties, through high performance on the applicable quality measure. We also believe that SNFs must have incentives to reduce hospital readmissions for their patients

no matter where their performance lies in comparison to their peers.

Taking those considerations into account, we analyzed the four exchange functions on which we have previously sought comment—linear, cube, cube root, and logistic—as well as variations of those exchange functions. We scored SNFs using historical SNFRM data and modeled SNFs' value-based incentive payments using each of the functions in turn. We evaluated the distribution of value-based incentive payments that resulted from each function, as well as the number of SNFs with positive payment adjustments and the value-based incentive payment percentages that resulted from each function. We also evaluated the functions' results for the statutory requirements in section 1888(h)(5)(C)(ii) of the Act, including the requirements in subclause (I) that the percentage be based on the SNF performance score for each SNF, in subclause (II) that the application of all such percentages results in an appropriate distribution, and in items (aa), (bb), and (cc) of subclause (II), specifying that SNFs with the highest rankings receive the highest value-based incentive payment amounts, that SNFs with the lowest rankings receive the lowest value-based incentive payment amounts, and that the SNFs in the lowest 40 percent of the ranking receive a lower payment rate than would otherwise apply.

In our analyses of the four baseline functions, we found that the logistic function maximized the number of SNFs with positive payment adjustments among SNFs measured using the SNFRM. We also found that the logistic function best fulfills the requirement that the SNFs in the lowest 40 percent of the ranking receive a lower payment rate than would otherwise apply, resulted in an appropriate distribution of value-based incentive payment percentages, and fulfilled the other statutory requirements described in this final rule. Specifically, we noted that the logistic function provided a broad range of SNFs with net-positive value-based incentive payments, and while it did not provide the highest value-based incentive payment percentage to the top performers of all the functions, we viewed the number of SNFs with positive payment adjustments as a more important consideration than the highest value-based incentive payment percentages being awarded.

We also considered alignment of VBP payment methodologies across fee-for-service Medicare VBP programs, including the Hospital VBP program and Quality Payment Program (QPP). We recognize that aligning payment methodologies would help stakeholders that use VBP payment information across care settings better understand the SNF VBP payment methodology. Both the Hospital VBP program and QPP use some form of a linear exchange function for payment. Three key program aspects that facilitate the use of a linear exchange function are the programs' number of measures, measure weights, and correlation across program measures. These three aspects in tandem contribute to the approximately normal distribution of scores expected in the Hospital VBP program and QPP. No single measure is the key driver that might ''tilt'' scores to a non-normal distribution. Since both programs are required to be budget neutral, our modeling estimates that scores translate into an approximately equal number of providers with positive payment adjustments and providers receiving a net payment reduction.

In contrast, the SNF VBP payment adjustment is driven, in part, by two specific SNF VBP statutory requirements: The program's use of a single measure; and the requirement that the total amount of value-based incentive payments for all SNFs in a fiscal year be between 50 and 70 percent of the total amount of reductions to payments for that fiscal year, as estimated by the Secretary. Our analysis of the linear exchange function showed that more SNFs would receive a net payment reduction than a payment incentive because the total amount available for incentive payments in a fiscal year is limited to between 50 and 70 percent of the total amount of the reduction to SNF payments for that fiscal year. The linear exchange function also results in the provision of a net payment reduction to a higher percentage of SNFs that exceeded the 50th percentile of national performance, relative to the logistic payment function. We believe that these findings are unique to the SNF VBP program, relative to other fee-for-service Medicare programs, because of the limitation on the total amount that we can use for incentive payments, coupled with the use of a single measure and the corresponding scoring distribution.

In addition to the four baseline functions described further above, we considered adjusting the linear function to be able to make positive payment adjustments to a greater number of SNFs. Specifically, we tested an alternative where we reduced the baseline linear function by 20 percent, then redistributed the resulting funds to the middle 40 percent of SNFs. We found that the use of this linear function with adjustment would enable us to make a positive payment adjustment to a slightly greater number of SNFs than we would be able to make using the logistic function. However, we were concerned with the additional complexity involved in implementing this type of two-step adjustment to the linear exchange function.

Taking all of these considerations into account, we proposed to adopt a logistic function for the FY 2019 SNF VBP Program and subsequent years. Under this policy, we would:

1. Estimate Medicare spending on SNF services for the FY 2019 payment year;

2. Estimate the total amount of reductions to SNFs' adjusted Federal per diem rates for that year, as required by statute;

3. Calculate the amount realized under the payback percentage policy (discussed further below);

4. Order SNFs by their SNF performance scores; and

5. Assign a value-based incentive payment multiplier to each SNF that corresponds to a point on the logistic exchange function that corresponds to its SNF performance score.

As we discussed in the proposed rule (82 FR 21085), we would model the logistic exchange function in such a form that the estimated total amount of value-based incentive payments equals not more than 60 percent of the amounts withheld from SNFs' claims. While the function's specific form would also depend on the distribution of SNF performance scores during the performance period, the formula that we used to construct the logistic exchange function and that we proposed to use for FY 2019 program calculations is:

$$y = \frac{1}{1 + e^{-0.1(x_i - 50)}}$$

where x_i is the SNF's performance score.

We sought public comments on this proposal, and in particular, on whether a linear function with adjustment would alternatively be feasible for the SNF VBP Program, potentially beginning with FY 2019. A discussion of these comments, along with our responses, appears below.

Comment: Some commenters supported the logistic exchange function, agreeing that it best incentivizes SNFs to improve continuously and allows for the greatest number of SNFs to receive net-positive payments. The commenters also agreed that the linear function with adjustment could create confusion, and requested that we provide an example calculation

of a provider's payment multiplier in the final rule.

Response: We thank the commenters for their support and feedback. In response to the commenters' request for an example, we can provide two hypothetical examples of SNFs' performance scores based on historical performance data and historical Medicare spending that would be subject to the Program. We would like to emphasize that the actual multipliers that will result from the calculation of the logistic exchange function for the FY 2019 Program year will depend on the distribution of SNF performance scores that result from the performance period as well as estimated Medicare spending subject to the Program for the FY 2019 payment year, and thus SNFs should not expect to receive the example multipliers below if their FY 2019 SNF performance scores approximate either of these examples.

A SNF with a baseline period SNFRM rate of 0.16980, which inverts to 0.83020, and a performance period SNFRM rate of 0.19989, which inverts to 0.80011, would, according to the formulas that we have adopted in previous regulations, receive 20.56057 points for achievement and 0 points for improvement since its measured performance declined. The higher of those two values is 20.56057, and that value would become the SNF's performance score. Based on the distribution of historical performance in the data sets that we analyzed, that SNF performance score translates into a value-based incentive payment multiplier of 0.150052 percent, which would be applied after the application of the 2% reduction required by section 1888(h)(6)(B).

Conversely, a SNF with a baseline period SNFRM rate of 0.18842, which inverts to 0.81158, and a performance period SNFRM rate of 0.17384, which inverts to 0.82616, would, according to the formulas that we have adopted in previous regulations, receive 70.23616 points for achievement and 4.78908 points for improvement. The higher of those two values is 70.23616, and that value would become the SNF's performance score. Based on the distribution of historical performance in the data sets that we analyzed, that SNF performance score translates into a value-based incentive payment multiplier of 2.64944 percent, which would be applied after the application of the 2 percent reduction required by section 1888(h)(6)(B) of the Act.

Comment: Two commenters requested additional details on the analyses that we conducted to reach the proposed policy, and also requested that we detail how the future transition to the SNFPPR would influence the distribution of incentive payments. One commenter suggested that we perform a ''dry run'' with the proposed methodology and provide confidential feedback reports to SNFs with the results.

Response: We thank the commenters for this feedback. We will consider providing a dry run or other additional information prior to the planned summer 2018 dissemination of Fiscal Year 2019 payment reports that will notify SNFs of the adjustments to their Medicare payments as required by section 1888(h)(7) of the Act. We also wish to inform the commenters that SNFs received confidential feedback reports with their calendar year 2015 baseline period readmission rates, as captured by the SNFRM, in early 2017. We continue to analyze the potential effects of the Program's transition to the SNFPPR, and we intend to provide additional details on the resulting distribution of value-based incentive payments in the future.

Comment: One commenter requested that we provide a scaling factor that we would use to ensure that payouts equate to 60 percent of the total amount withheld from SNFs' Medicare payments. The commenter also recommended that we not consider the cube exchange function, noting that it would result in extremely high payouts to top providers who may be outliers, and suggested that we provide the slope of each alternative function listed in the rule.

Response: We thank the commenter for the feedback on the exchange function form, and we agree with the commenter that the cube function results in an undesirable distribution of incentive payments to SNFs. As discussed further below, we are finalizing the logistic exchange function for the FY 2019 Program.

In response to the commenter's request that we provide the scaling factor that we would use to ensure that value-based incentive payments under the Program equal the 60 percent payback percentage that we proposed and are finalizing in this final rule, we note that the distribution of incentive payments provided under the Program depends entirely on the distribution of SNFs' performance on the applicable measure during the baseline and performance periods. We are unable to provide a scaling factor for the FY 2019 program year at this time because the performance period (CY 2017) has not concluded yet, though we may consider doing so after the performance period has concluded. We intend to provide additional detail on the distribution of SNF performance scores and the resulting value-based incentive payment percentages, potentially including the scaling factor, in the future.

After consideration of the public comments that we have received, we are finalizing the logistic exchange function as proposed.

(2) Payback Percentage

Section 1888(h)(6)(A) of the Act requires the Secretary to reduce the adjusted federal per diem rate determined under section 1888(e)(4)(G) of the Act otherwise applicable to a SNF for services furnished by that SNF during a fiscal year by the applicable percent (which, under section 1888(h)(6)(B) of the Act is 2 percent for FY 2019 and succeeding fiscal years) to fund the value-based incentive payments for that fiscal year. Section 1888(h)(5)(C)(ii)(III) of the Act further specifies that the total amount of value-based incentive payments under the Program for all SNFs in a fiscal year 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 that fiscal year under the Program, as estimated by the Secretary. Thus, we must decide what percentage of the total amount of the reductions to payments for a fiscal year we will pay as value-based incentive payments to SNFs based on their performance under the Program for that fiscal year.

As with our exchange function policy described in this final rule, we view the important factors when specifying a payback percentage to be the number of SNFs that receive a positive payment adjustment, the marginal incentives for all SNFs to reduce hospital readmissions and make broad-based care quality improvements, and the Medicare Program's long-term sustainability through the additional estimated Medicare trust fund savings. We intend for the proposed payback percentage to appropriately balance these factors. We analyzed the distribution of value-based incentive payments using historical data, focusing on the full range of available payback percentages.

Taking these considerations into account, we proposed that the total amount of funds that would be available to pay as value-based incentive payments in a fiscal year would be 60 percent of the reductions to payments otherwise applicable to SNF Medicare payments for that fiscal year, as estimated by the Secretary. We believe that 60 percent is the most appropriate payback percentage to balance the considerations described in the proposed rule.

We noted that we intend to closely monitor the effects of the payback percentage policy on Medicare beneficiaries, on participating SNFs, and on their measured performance. We also stated that we intend to consider proposing to adjust the payback percentage in future rulemaking. In our consideration, we would include the Program's effects on readmission rates, potential unintended consequences of SNF care to beneficiaries included in the measure, and SNF profit margins. Since the SNF VBP Program is a new, single measure value-based purchasing program and will continue to evolve as we implement it—including, for example, changing from the SNFRM to the SNFPPR as required by statute—we stated that we intend to evaluate its effects carefully.

We noted also that the Medicare Payment Advisory Commission's research has shown that for-profit SNFs' average Medicare margins are significantly positive,[53] though not-for-profit SNFs' average Medicare margins are substantially lower, and we requested comment on the extent to which that should be considered in our policy. We also recognized that there is some evidence that not-for-profit SNFs tend to perform better on measures of hospital readmissions than for-profit SNFs,[54] and we requested comment on whether our proposed payback percentage appropriately balances Medicare's long-term sustainability with the need to provide strong incentives for quality improvement to top-performing but lower-margin SNFs.

We sought public comments on this proposal. A discussion of these comments, along with our responses, appears below.

Comment: Several commenters recommended that we finalize a 70 percent payback percentage, stating that the largest possible incentive pool will have a larger impact on changing practices and will provide a softer landing for participating providers. Commenters were also concerned that the actual payback percentage may be different than 60 percent if our forecast turns out to be erroneous, and suggested that we instead calculate confidence intervals around the payback percentage.

Other commenters stated that the greatest percentage of dollars should be made available to facilities that invest in their staffs and are therefore top performers, noting also that MedPAC analysis shows that top performers are not enjoying large margins on their Medicare business, and that a larger incentive pool would provide more incentive dollars to high-performing SNFs. Commenters also stated that the Medicare Trust Fund will benefit from reduced hospital spending resulting from lower readmission rates.

Some commenters recommended that we adopt a 70 percent payback percentage and that we use the other 30 percent of amounts withheld from SNFs' Medicare payments to fund quality improvement initiatives. One commenter cited the reduction to SNF PPS rates to fund physician payments, significant MDS changes that will drive staffing and training costs, and the possible revamping of the RUG methodology, as rationale for selecting the maximum possible payback percentage under the Program. The commenter stated that these changes mean that CMS should not make any additional funding reductions beyond those absolutely required.

Response: We thank the commenters for this feedback. Section 1888(h)(5)(C)(ii)(III) of the Act provides that the total amount of value-based incentive payments for all skilled nursing facilities in a fiscal year must be greater than or equal to 50 percent, but not greater than 70 percent of the total amount of the reductions to SNFs' Medicare payments for that fiscal year, as estimated by the Secretary. We are confident that our payback percentage can be implemented accurately, based on our experience estimating the total amount available for value-based incentive payments under the Hospital Value Based Purchasing program. We intend to utilize a similar methodology for the SNF VBP Program by using the most currently available historic SNF claims to estimate the pool of available funds, the finalized payback percentage and corresponding withhold percentage, and the finalized payment exchange function. It is important to note that the 50 to 70 percent range is based on national Medicare spending using the entire population of about 15,000 SNF claims data, and that large data set means that we are able to estimate the payment exchange function that applies the finalized withhold and payback percentage with a high degree of accuracy.

In response to comments that we finalize 70 percent as the payback percentage for the Program, we intended for the proposed payback percentage to balance several policy considerations, including the number of SNFs that receive a positive payment adjustment, the marginal incentives for SNFs to reduce hospital readmissions and make broad-based care quality improvements, and the long-term financial sustainability of the Medicare Program. We do not believe that finalizing a 70 percent payback percentage appropriately balances those factors, particularly the Medicare Program's long-term sustainability, because it results in significantly higher Medicare spending under the Program in a provider sector already experiencing significantly positive Medicare margins. We believe that the other policies we are finalizing in this final rule, including the logistic exchange function, ensure that we provide strong incentives for quality improvement to SNFs within the constraints imposed by the SNF VBP Program's statute.

We intend to carefully monitor the Program's effects on SNFs' care quality improvement efforts and providers' Medicare margins. We would also like to clarify that the savings realized from the Program (that is, the 30 to 50 percent of the amounts withheld from SNFs' claims) are not authorized to be distributed separately for quality improvement initiatives, and are instead retained in the Medicare Trust Fund and used for other Medicare Program purposes authorized by statute.

Comment: One commenter stated that it is unnecessary to adjust the payback percentage based on facility ownership type, stating that the data do not support differential treatment among SNFs.

Response: We thank the commenter for this feedback. However, we would like to clarify that we did not propose to adjust the payback percentage based on facility ownership type. We will monitor the Program's effects on SNFs carefully.

Comment: Two commenters requested that we provide additional information regarding the empirical modeling used to inform our proposed policies, including the proposed 60 percent payback percentage. The commenters stated that the explanations we provided in the proposed rule do not provide sufficient transparency into our decision-making.

Response: We believe that we released sufficient information in the proposed rule to give commenters enough information to submit meaningful comments on our selection of the 60 percent payback proposal, including the

[53] Medicare Payment Advisory Commission, March 2017 Report to the Congress, ch. 8: Skilled nursing facility services, Table 8–6. *http://medpac.gov/docs/default-source/reports/mar17_entirereport.pdf.*

[54] Neuman MD, Wirtalla C, Werner RM. Association Between Skilled Nursing Facility Quality Indicators and Hospital Readmissions. *JAMA.* 2014;312(15):1542–1551. doi:10.1001/jama.2014.13513. Retrieved from *http://jamanetwork.com/journals/jama/fullarticle/1915609.*

considerations that we took into account when developing our proposed policy (82 FR 21086) and the detailed analytical results that we presented in the proposed rule's regulatory impact analysis (82 FR 21094 through 21095). However, we are in the process of compiling additional empirical modeling information and intend to make that information available to the public on the CMS.gov Web site no later than November 2017.

Comment: One commenter stated that CMS should redistribute the full amount withheld from SNFs' claims in incentive payments rather than 50 to 70 percent. The commenter also stated that the requirement that the bottom 40 percent of SNFs not be eligible for incentive payments is unfair, and requested that we provide details on the funds not being redistributed to SNFs.

Response: We thank the commenter for this feedback. However, the requirements that the total amount available for value-based incentive payments in a fiscal year be greater than or equal to 50 percent, but not greater than 70 percent, as well as the requirement that the SNFs ranked in the lowest 40 percent receive a payment rate for services furnished during a fiscal year that less than the payment rate they would have received otherwise for that fiscal year, are statutory in origin. As a result, we do not believe we have the discretion to redistribute the full amount withheld from SNFs' claims as incentive payments or to pay SNFs in the bottom 40 percent the same or a higher rate than they would have otherwise received in the absence of the Program.

In response to the commenter's question about funds not being redistributed to SNFs (that is, the 30 to 50 percent of SNFs' Medicare payments remaining after the payment withhold is determined), as we stated above, those funds are not authorized to be distributed separately for quality improvement initiatives, and are instead retained in the Medicare Trust Fund and used for other Medicare Program purposes authorized by statute.

Comment: Commenter agreed in general with our view that the Program will be most effective if it offers incentive payments to SNFs rather than payment penalties.

Response: We believe that the policies we are finalizing in this final rule, including the payback percentage and the use of the logistical exchange function, will enable us to offer incentive payments to a broad number of SNFs while balancing that consideration with the Medicare Program's long-term sustainability.

After consideration of the public comments that we received, we are finalizing the payback percentage for the FY 2019 SNF VBP program as 60 percent of the total amount of the reduction to SNFs' Medicare payments for that fiscal year, as estimated by the Secretary. We will set the exchange function such that we remit 60 percent of the estimated total amount withheld from SNFs' Medicare payments as value-based incentive payments, though each individual SNF's value-based incentive payment percentage will vary according to its SNF performance score.

g. SNF VBP Reporting

(1) Confidential Feedback Reports

We refer readers to the FY 2017 SNF PPS final rule (81 FR 52006 through 52007) for discussion of our intention to use the QIES system CASPER files to fulfill the requirement in section 1888(g)(5) of the Act that we provide quarterly confidential feedback reports to SNFs on their performance on the Program's measures. We also responded in that final rule to public comments on the appropriateness of the QIES system.

We provided SNFs with a test report in September 2016, followed by data on SNFs' CY 2013 performance on the SNFRM in December 2016 and SNFs' CY 2014 performance on the SNFRM in March 2017. We then provided SNFs with their CY 2015 performance on the SNFRM in June 2017, along with a supplemental workbook providing patient-level data. We intend to continue providing SNFs with their performance data each quarter as required by the statute.

We sought feedback from SNFs on the contents of the quarterly reports and what additional elements, if any, we should consider including that would be useful for quality improvement efforts. We specifically sought comment on what patient-level data would be most helpful to SNFs if they were to request such data from us as part of their quality improvement efforts. A discussion of these comments, along with our responses, appears below.

Comment: Several commenters expressed their view that specific facility-level and patient-level data elements should be provided in quarterly confidential feedback reports. Other commenters expressed support for both the facility level and patient identifiers that we are providing. One commenter suggested that dual eligibility status for patients be provided in quarterly confidential feedback reports. Another commenter requested that we provide additional information in our quarterly confidential feedback reports, including national benchmarks used to calculate achievement and improvement scores, peer ranking information, and SNF-specific trend data and top causes of readmission. This commenter also requested that quarterly confidential feedback reports contain the SNF VBP Program measure calculated using 12 rolling months of data, and that we update such calculations quarterly. Lastly, one commenter requested that reports be provided more frequently than quarterly.

Response: We are currently providing many patient-level indicators to SNFs as part of the quarterly reports process, and since we began that reporting during the public comment period on the proposed rule, we believe some commenters may have erroneously believed that we did not intend to provide patient-level data. June 2017 quarterly confidential feedback reports and supplemental workbooks included the following patient-level data: Patient identifiers (Health Insurance Claim Number [HICN], Sex, Age); Index SNF information (admission/discharge dates, discharge status code); Prior proximal hospital information CMS Certification Number [CCN], admission/discharge dates, principal diagnosis); Readmission hospital information (CCN, admission/discharge dates, principal diagnosis); and SNFRM risk-adjustment factors. The following facility-level information is also included: Number of Eligible Stays, Number of Unplanned Readmissions, Observed Readmission Rate, Predicted Number of Readmissions, Expected Number of Readmissions, Standardized Risk Ratio (SRR), National Average Readmission Rate, RSRR. We will take the commenter's request to report patient's dual eligibility status under consideration for future reports.

We intend to publish performance standards for each program year in the SNF PPS final rule, and we intend to provide peer ranking information to SNFs as it becomes available. We believe that providing the SNF VBP program measure rate calculations using 12 rolling months of data updated quarterly would create confusion among providers regarding which of these rates would be used to calculate value-based incentive payments for a specific program year. We strive to provide information that is as user-friendly as possible and will take the commenter's request for SNF-specific trend data and top causes of readmission under consideration. Finally, while we appreciate the need for frequent updates, monthly reports containing this information are not logistically

feasible at this time. However, we continue to look for ways in which we may provide this information more frequently in the future.

We thank the commenters for this feedback.

(2) Review and Corrections Process: Phase Two

In the FY 2017 SNF PPS final rule (81 FR 52007 through 52009), we adopted a two-phase review and corrections process for SNFs' quality measure data that will be made public under section 1888(g)(6) of the Act and SNF performance information that will be made public under section 1888(h)(9) of the Act. We explained that we would accept corrections to the quality measure data used to calculate the measure rates that is included in any SNF's quarterly confidential feedback report, and also that we would provide SNFs with an annual confidential feedback report containing the performance information that will be made public. We detailed the process for requesting Phase One corrections and finalized a policy whereby we would accept Phase One corrections to SNFs' quarterly reports through March 31 following the report's issuance via the CASPER system.

In the proposed rule (82 FR 21086 through 21087), we proposed additional specific requirements for the Phase Two review and correction process that we are finalizing in this final rule. Specifically, we proposed to limit Phase Two correction requests to the SNF's performance score and ranking because all SNFs would have already had the opportunity to correct their quality measure data through the Phase One corrections process.

We also proposed to provide these reports to SNFs at least 60 days prior to the FY involved. SNFs will not be allowed to request corrections to their value-based incentive payment adjustments. However, we stated that we will make confirming corrections to a SNF's value-based incentive payment adjustment if a SNF successfully requests a correction to its SNF performance score.

As with Phase One, we proposed that Phase Two correction requests must be submitted to the *SNFVBPinquiries@cms.hhs.gov* mailbox, and must contain the following information:

- SNF's CMS Certification Number (CCN);
- SNF Name;
- The correction requested and the SNF's basis for requesting the correction.

Specifically, the SNF must identify the error for which it is requesting correction, and explain the reason for requesting the correction. The SNF must also submit documentation or other evidence, if available, supporting the request. As noted above, corrections requested during Phase Two will be limited to SNFs' performance score and ranking. However, we noted that the *SNFVBPinquiries@cms.hhs.gov* mailbox cannot receive secured email messages. If any SNF believes it needs to submit patient-sensitive information as part of a correction request, we requested that the SNF contact us at the mailbox to arrange a secured transfer.

We further proposed that SNFs must make any correction requests no later than 30 days following the date of our posting of their annual SNF performance score report via the QIES system CASPER files. For example, if we post the reports on August 1, 2017, SNFs must review these reports and submit any correction requests by 11:59 p.m. Eastern Standard Time on August 31, 2017 (or the next business day, if the 30th day following the date of the posting is a weekend or federal holiday). We stated that we would not consider any requests for corrections to SNF performance scores or rankings that are received after this deadline.

We proposed to review all timely Phase Two correction requests that we receive and provide responses to SNFs that have requested corrections as soon as practicable. We also proposed to issue an updated SNF performance score report to any SNF that requests a correction with which we agree, and if necessary, to update any public postings on *Nursing Home Compare* and value-based incentive payment percentages, as applicable.

We sought public comments on this proposed Phase Two corrections process. A discussion of these comments, along with our responses, appears below.

Comment: Some commenters recommended that SNFs be provided access to the information used to calculate their SNFRM scores and estimate their payment adjustment factors based on the payment exchange function. Commenters stated that SNFs' may wish to replicate their SNF VBP performance scores as closely as possible, and requested that SNFs receive their predicted and expected readmission rates, national average readmission rates, and RSRRs for both the baseline and performance periods, as well as the cut points used to determine performance standards. Commenters explained that such information will help SNFs be more confident about their final payment adjustments as well as to understand what they need to do to improve their SNFRM scores and payment adjustments.

Response: We thank the commenters for this feedback. While it is correct that SNFs cannot calculate their own risk-standardized readmission rates because such a calculation would require national stay-level data, including risk-adjustment information, we believe that the additional patient-level and facility-level information that we are now providing to SNFs (as discussed further above) along with their quarterly reports will be useful to SNFs with their quality improvement efforts. We also provide SNFs with their predicted and expected readmission rates, national average readmission rates, and RSRRs in their quarterly confidential feedback reports and supplemental workbooks. We welcome commenters' continued feedback on the contents of the supplemental workbooks containing facility-level and patient-level data that accompany the quarterly confidential feedback reports.

Comment: One commenter requested that we provide Phase Two scoring reports to SNFs as soon as possible if we elect to change from calendar year to fiscal year performance periods to ensure that SNFs have sufficient time to review those reports and submit correction requests.

Response: We thank the commenter for this suggestion, and we will strive to provide SNF performance score reports to SNFs as quickly as possible. We note, however, that it is time consuming for us to complete the tasks necessary to ensure that the information contained in the performance score reports is accurate. At this time, we do not believe we can feasibly provide SNF performance score reports prior to the statutorily-required deadline described in section 1888(h)(7) of the Act that SNFs be notified of the adjustments to their Medicare payments as a result of the Program. We will consider future improvements if information technology and claims processing improvements allow for earlier dissemination of this information to SNFs.

Comment: One commenter supported our review and correction policies in general, but was unsure how a SNF could challenge its SNF performance score or ranking since SNFs do not receive patient-level data, and requested that we make such data available to SNFs. The commenter noted that additional information could be useful to SNFs, including their predicted readmission rate, their expected readmission rate, the national average, the SNF's baseline and performance period rates, the SNF's ranking, and the

achievement and improvement thresholds.

Response: Our intention is to provide SNFs with the patient level data and associated data elements that the commenter suggests in the SNF performance score reports scheduled for delivery next year, though we note, as stated above, that we are now providing patient-level data in SNFs' quarterly confidential feedback reports. We welcome commenters' continued feedback on those data and any other elements that may be helpful to SNFs with their quality improvement efforts.

After consideration of the public comments that we received, we are finalizing the Phase Two review and corrections process, as proposed.

(3) SNF VBP Program Public Reporting

We refer readers to the FY 2017 SNF PPS final rule (81 FR 52009) for discussion of the statutory requirements governing the public reporting of SNFs' performance information under the SNF VBP Program. We also sought and responded to public comments on issues that we should take into account when posting performance information on *Nursing Home Compare* or a successor Web site.

We proposed to begin publishing SNF performance information under the SNF VBP Program on *Nursing Home Compare* not later than October 1, 2017. We stated that we would only publish performance information for which SNFs have had the opportunity to review and submit corrections. We sought comments on this proposal. A discussion of these comments, along with our responses, appears below.

Comment: One commenter supported posting SNF performance scores on Nursing Home Compare, but opposed posting quality measure performance scores, including achievement/improvement scores. The commenter stated that achievement and improvement scores are not required by statute to be publicly posted and could be confusing to the public. The commenter also noted that the Program's quality measures differ from those already posted on *Nursing Home Compare,* and stated that having multiple rehospitalization rates would not be ideal.

Response: We thank the commenter for this feedback. We note that section 1888(g)(6) of the Act directs the Secretary to make SNF-specific information available to the public, including information on measure-level performance, and we will consider the commenter's views as we develop our plans for public reporting of SNF VBP data in the future.

Comment: Commenter requested that we clarify our intentions for public reporting of SNF VBP information on *Nursing Home Compare,* wondering if this information will replace the current readmission rate information and definitions on the site or if SNF VBP information will be added to the site's current content. The commenter also expressed frustration that CMS is using multiple definitions of readmissions for different programs, and suggested that we align our efforts.

Response: We intend to publish SNF VBP performance information on *Nursing Home Compare* or a successor Web site as directed by the SNF VBP Program's statute. We are cognizant of the possibility for confusion, and we intend to align our efforts as much as possible across programs, including giving providers sufficient information to aid them in distinguishing between the readmission measures on *Nursing Home Compare.*

Comment: Commenter encouraged us to publish as much information as possible on *Nursing Home Compare*, including readmissions rates, achievement and improvement points, SNF performance scores, rankings, and payment adjustments. The commenter noted that many of these data points are available for the Hospital VBP and Readmissions Reduction Programs, and noted that the public should expect the same transparency for SNFs.

Response: We thank the commenter for this feedback and will take it into consideration as we continue developing our public reporting plans.

After consideration of the public comments that we have received, we are finalizing our public reporting policy as proposed.

(4) Ranking of SNFs' Performance

We refer readers to the FY 2017 SNF PPS final rule (81 FR 52009) for discussion of the statutory requirement that we rank SNFs based on their performance on the Program. In that rule, we discussed the statutory requirements to order SNF performance scores from low to high and publish those rankings on both the *Nursing Home Compare* and QualityNet Web sites, and to publish the ranking after August 1, 2018, when performance scores and value-based incentive payment adjustments will be made available to SNFs. We intend to publish the ranking for each program year once performance scores and value-based incentive payment adjustments are made available to SNFs.

Having considered those statutory requirements, we proposed to rank SNFs for the FY 2019 program year and to publish the ranking after August 1, 2018. We further proposed that the ranking include the following data elements:

- Rank,
- Provider ID,
- Facility name,
- Address,
- Baseline period (CY 2015) risk-standardized readmission rate,
- Performance period (CY 2017) risk-standardized readmission rate,
- Achievement score,
- Improvement score, and
- SNF performance score.

We believe that these data elements will provide consumers and other stakeholders with the necessary information to evaluate SNFs' performance under the program, including each component of the SNF performance score, including both achievement and improvement. We sought public comments on these proposals. We stated in the proposed rule that we would address rankings for future program years in subsequent rulemaking. A discussion of these comments, along with our responses, appears below.

Comment: One commenter stated its belief that we must publish the FY 2019 program ranking not later than August 1, 2018, rather than after August 1 as we described in the proposed rule. The commenter noted that publishing the ranking by that date will provide all stakeholders with sufficient time to review the ranking prior to the fiscal year.

Response: Section 1888(h)(9) of the Act does not provide a specific deadline for public reporting of SNF performance scores and the ranking for a given fiscal year. Our intention in stating that we would publish the ranking after August 1, 2018, was only to communicate that we would publish the ranking publicly after SNFs have been notified of their SNF performance scores, value-based incentive payment percentages, and ranking as required by section 1888(h)(7) of the Act, which must take place not later than 60 days prior to the fiscal year involved.

After consideration of the public comments, we are finalizing the SNF VBP Program's ranking policies as proposed.

4. Survey Team Composition

a. Background

To participate in the Medicare and Medicaid programs, long term care facilities, including skilled nursing facilities (SNFs) in Medicare and nursing facilities (NFs) in Medicaid, must be certified as meeting Federal

participation requirements, which are specified in 42 CFR part 483. Section 1864(a) of the Act authorizes the Secretary to enter into agreements with state survey agencies to determine whether SNFs meet the federal participation requirements for Medicare and section 1902(a)(33)(B) of the Act provides for state survey agencies to perform the same survey tasks for NFs participating or seeking to participate in the Medicaid program. Surveys are performed directly by us and also under contract for certain surveys. The results of these surveys are used by us and the Medicaid state agency as the basis for a determination to enter into, deny, or terminate a provider agreement with the facility, or to impose an enforcement remedy or remedies on a facility, as appropriate, for failure to be in substantial compliance with federal participation requirements. To assess compliance with federal participation requirements, surveyors conduct onsite inspections (surveys) of facilities. In the survey process, surveyors gather evidence and directly observe the actual provision of care and services to residents and the effect or possible effects of that care, or lack thereof, to assess whether the care provided meets the assessed needs of individual residents.

Sections 1819(g) and 1919(g) of the Act, and corresponding regulations at 42 CFR part 488, subpart E, specify the requirements for the types and periodicity of surveys that are to be performed for each facility. Specifically, sections 1819(g)(2) and 1919(g)(2) of the Act reference standard, special, and extended surveys. Sections 1819(g)(2)(E) and 1919(g)(2)(E) of the Act specify that surveys under section 1819(g)(2) of the Act in general must consist of a multidisciplinary team of professionals, including a registered nurse. In addition, the statutory requirements governing the investigation of complaints and for monitoring on-site a SNF's or NF's compliance with participation requirements are found in sections 1819(g)(4) and 1919(g)(4) of the Act and § 488.332.

These sections specify that a specialized team, including an attorney, an auditor, and appropriate health care professionals may be maintained and utilized in the investigation of complaints for the purpose of identifying, surveying, gathering and preserving evidence, and carrying out appropriate enforcement actions against SNFs and NFs, respectively.

Consistent with the statutory provisions noted above, two separate regulations directly address survey team composition. Section 488.314, Survey Teams, reflects the statutory language under sections 1819(g)(2)(E)(i) and 1919(g)(2)(E)(i) of the Act, and states that ''[s]urvey teams must be conducted by an interdisciplinary team of professions, which must include a registered nurse.'' Section 488.332, Investigation of Complaints of Violations and Monitoring of Compliance, reflects the statutory language under sections 1819(g)(4) and 1919(g)(4) of the Act, and states that the state survey agency may use a specialized team, which may include an attorney, auditor, and appropriate health professionals, but not necessarily a registered nurse, to investigate complaints and conduct on-site monitoring. A survey conducted to monitor on-site a SNF's or NF's compliance with participation requirements, such as a revisit survey to determine whether a noncompliant facility has achieved substantial compliance, is also subject to the provisions of § 488.332, and not § 488.314.

Section 488.308(e) also addresses complaint investigations, but as currently written, it combines special surveys, which are authorized under sections 1819(g)(2)(A)(iii)(II) and 1919(g)(2)(A)(iii)(II) of the Act, with the requirements associated with the investigations of complaints, which are governed by sections 1819(g)(4) and 1919(g)(4) of the Act. In the statute, ''special surveys'' are referenced at sections 1819(g)(2)(A)(iii)(II) and 1919(g)(2)(A)(iii)(II) of the Act, while the investigation of complaints is referenced at sections 1819(g)(4) and 1919(g)(4) of the Act.

The regulations as currently written do not clearly indicate which survey team requirement applies to complaint surveys. The language at § 488.314 could be broadly interpreted to cover the survey team composition for all surveys, including those used to investigate a complaint. Such an interpretation, however, would ignore the provisions of § 488.332, which allow a state survey agency to utilize a specialized investigative team that does not necessarily include a registered nurse to survey a facility in connection with a complaint investigation. The placement of surveys to investigate a complaint together with special surveys under § 488.308(e) further places into question which survey team requirement applies to complaint surveys. However, CMS' State Operations Manual (SOM) (Internet Only Manual Pub. 100–07) notes that ''Section 488.332 provides the Federal regulatory basis for the investigation of complaints about nursing homes,'' thus indicating CMS' view that provisions related to survey team composition in § 488.332 apply to complaint surveys. *See* SOM, Ch. 5, Section 5300; *see also* SOM, Ch. 7, Sections 7203.5 and 7205.2(3); SOM, Appendix P, II.B.4A.

The lack of clarity as to which regulatory provision, that is, § 488.314 or § 488.332, applies to the survey team composition related to the investigation of complaints has been the cause of recent administrative litigation. We thus believe that regulatory changes are needed to clarify that only surveys conducted under sections 1819(g)(2) and 1919(g)(2) of the Act are subject to the requirement at § 488.314 that a survey team consist of an interdisciplinary team that must include a registered nurse. Complaint surveys and surveys related to on-site monitoring, including revisit surveys, are subject to the requirements of sections 1819(g)(4) and 1919(g)(4) of the Act and § 488.332, which allow the state survey agency to use a specialized investigative team that may include appropriate health care professionals but need not include a registered nurse.

b. Major Provisions

We proposed to make changes to §§ 488.30, 488.301, 488.308, and 488.314 to clarify the regulatory requirements for team composition for surveys conducted for investigating a complaint and to align regulatory provisions for investigation of complaints with the statutory requirements found in sections 1819 and 1919 of the Act.

(a) Proposed revision of the definition of ''complaint survey'' under § 488.30 to add a provision stating that the requirements of sections 1819(g)(4) and 1919(g)(4) of the Act and § 488.332 apply to complaint surveys.

(b) Proposed revision of the definition of ''abbreviated standard survey'' under § 488.301 to clarify that abbreviated standard surveys conducted to investigate a complaint or to conduct on-site monitoring to verify compliance with participation requirements are subject to the requirements of § 488.332.

(c) Proposed relocation of the requirements included in § 488.308(e)(2) and (3) related to surveys conducted to investigate a complaint from under the heading ''Special Surveys'' to a new paragraph (f), titled ''Investigations of Complaints.''

(d) Proposed revision of the language at § 488.314(a)(1) to specify that the team composition requirements at § 488.314(a)(1) apply only to surveys under sections 1819(g)(2) and 1919(g)(2) of the Act.

Commenters submitted the following comments related to the proposed rule's discussion of the Survey Team Composition. A discussion of these comments, along with our responses, appears below.

Comment: We received one comment supporting our proposal and the commenter agreed with our clarification on the survey team composition. The commenter further stated that states should be able to determine the composition of the survey team based on the complaint received and the purpose of the revisit to determine compliance.

Response: We want to thank the commenter for their support of our clarifications to the survey team composition. We agree that the states should be able to determine which professional would be most appropriate based on the complaint received, such as a registered nurse for clinical concerns, a dietitian for dietary concerns, or a pharmacist for medication issues for example.

Comment: We received several comments recommending us to consider adding a Registered Nurse (RN) to all survey teams. Multiple commenters stated that an RN should be the individual to investigate any alleged incident. Another commenter stated that they believed statutory language is clear that a survey team must include a registered professional nurse, and that the citation of clinical violations should be observed and made by a registered professional nurse. One commenter recommended that we add a requirement for a psychosocial professional to be on each team in addition to a registered nurse. One commenter also recommended that in addition to having an RN on the survey team, the team should also include an additional professional based on the complaint type.

Response: We appreciate the feedback from the commenters regarding the suggestion to have an RN on all surveys or to add a psychosocial professional to the team, but the proposed change to the language regarding survey team composition is not to change the composition of survey teams, but to clarify the requirement that survey teams conducted by an interdisciplinary team of professionals, including a registered nurse applies only to surveys under sections 1819(g)(2) and 1919(g)(2) of the Act and does not apply to complaint surveys in which the appropriate professional would be used to conduct the investigation based on the type of allegation.

Comment: One commenter stated that they disagreed with our interpretation of its statutory authority. The commenter stated that they believed statutory requirement for a registered nurse on this team is clear and that the statute draws no distinction between a complaint survey and a standard survey. The commenter further stated that citations of clinical violations should be observed and confirmed or dismissed by a registered professional nurse based upon his or her clinical judgment.

Response: The preamble to the proposed rule states that the proposed change is to clarify the requirement that survey teams conducted by an multidisciplinary team of professionals, including a registered nurse, applies only to surveys described under sections 1819(g)(2) and 1919(g)(2) of the Act and does not apply to the investigation of complaints. The authority for complaint surveys arises under sections 1819(g)(4) and 1919(g)(4) of the Act, which authorizes the State survey agency to use a specialized team, which includes appropriate healthcare professionals that may or may not, if not required, include a registered nurse, for purposes of, among other things, ''surveying'' noncompliant facilities. As discussed in the preamble, we believe these clarifying changes are consistent with the statutory provisions of sections 1819(g)(2) and (g)(4) and 1919(g)(2) and (g)(4) of the Act, as well as our long standing interpretation of the statute, as expressed in the implementation of current regulations at §§ 488.314 and 488.332 and the State Operations Manual (''SOM''). We believe that if we were to require a registered nurse on all surveys including those that are meant to investigate complaint allegations, it would place an undue burden on the resources of state survey agencies and render the statutory language under sections 1819(g)(4) and 1919(g)(4) of the Act as meaningless. In addition, as previously mentioned, we believe that the statute enables us to determine which professional would be most appropriate to investigate complaint allegations based on the nature of the complaint allegation received.

Comment: We received one comment requesting a revision based on the decision at DAB No. CR4670 (2016) (H.H.S.), 2016 WL 499224, in which an Administrative Law Judge provided an interpretation of the survey composition provisions in the statute and current regulations.

Response: We appreciate the commenter's reference to this case, however the ALJ decision is currently being reviewed by the Departmental Appeals Board Appellate Division and therefore we cannot comment on this case at this time.

Based on the comments received, we are proceeding with the finalization of our proposal without any changes.

5. Correction of the Performance Period for the National Healthcare Safety Network (NHSN) Healthcare Personnel (HCP) Influenza Vaccination Immunization Reporting Measure in the End-Stage Renal Disease (ESRD) Quality Incentive Program (QIP) for Payment Year (PY) 2020

In the CY 2017 ESRD PPS final rule (81 FR 77834), we finalized that the performance period for the NHSN Healthcare Personnel Influenza Vaccination Reporting Measure for Payment Year (PY) 2020 would be from October 1, 2016, through March 31, 2017 (81 FR 77915). We proposed to revise that performance period so that it aligns with the schedule we previously set for this measure. Specifically, we previously finalized that for the PY 2018 ESRD QIP, the performance period for this measure would be from October, 1, 2015 through March 31, 2016, which is consistent with the length of the 2015–2016 influenza season (79 FR 66209), and that for the PY 2019 ESRD QIP, the performance period for this measure would be from October, 1, 2016 through March 31, 2017, which is consistent with the length of the 2016- 2017 influenza season (80 FR 69059 through 69060). Maintaining the performance period we finalized in the CY 2017 ESRD PPS final rule would result in scoring facilities on the same data twice, and would not be consistent with our intended schedule to collect data on the measure in successive influenza seasons. Therefore, we proposed to revise the performance period for the NHSN HCP Influenza Vaccination Reporting Measure for the PY 2020 ESRD QIP. Specifically, we proposed that for the PY 2020 ESRD QIP, the performance period for this measure would be October 1, 2017, through March 31, 2018, which is consistent with the length of the 2017–2018 influenza season.

We sought comments on this proposal. A discussion of these comments, along with our responses, appears below.

Comment: Commenters were generally supportive of our proposal to set the performance period as October 1, 2017 through March 31, 2018 because it is consistent with the length of the 2017–2018 influenza season, however they stated that to be truly consistent with the influenza season and the standard practice of administering the vaccine, the performance period for the measure should be aligned with the CDC's recommendations that

vaccination occur as early as possible to protect against infection. They stated that without including the phrase ''or when the vaccine becomes available,'' the measure penalizes facilities that provide the vaccine as soon as it becomes available in August or September. One commenter also stated that not making this change could place patients at increased risk early in the influenza season.

Response: As stated in the CY 2015 ESRD PPS final rule (79 FR 66207) in response to a commenter who was concerned about whether vaccinations received before October 1 would qualify under this measure, ''the performance period for the denominator (the number of healthcare personnel working in a facility) is from October 1 through March 31. However, the numerator measurement (vaccination status) includes vaccines obtained 'as soon as the vaccine is available.' As a result, a Healthcare Personnel (HCP) working at the facility as of October 1 who was vaccinated in September would be considered vaccinated for the performance period under this measure'' (79 FR 66207). As a result, facilities will not be penalized for providing the vaccine as soon as it becomes available and patients will not be placed at an increased risk at any point during the influenza season due to the vaccination status of HCPs working in the facility.

After carefully considering the comments received we are finalizing the Performance Period for the NHSN HCP Influenza Vaccination Reporting Measure for the ESRD QIP for Payment Year 2020 as proposed.

IV. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501 *et seq.*), we are required to publish a 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, PRA section 3506(c)(2)(A) 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 burden estimates.
- The quality, utility, and clarity of the information to be collected.
- Our effort to minimize the information collection burden on the affected public, including the use of automated collection techniques.

We solicited public comment in the FY 2018 SNF PPS proposed rule on each of the section 3506(c)(2)(A)-required issues for the following information collection requirements (ICRs).

A. Information Collection Requirements (ICRs)

1. ICRs Regarding the SNF VBP Program

As discussed in the FY 2016 SNF PPS final rule (80 FR 46473) and the FY 2017 SNF PPS final rule (81 FR 52049 through 52050), we have specified claims-based measures to fulfill the SNF VBP Program's requirements. As required by the SNF VBP Program's statute, we will score SNFs' performance on these measures in order to make value-based incentive payments to SNFs beginning in FY 2019.

In this final rule, we are finalizing additional policies for the SNF VBP Program, including performance standards and performance/baseline periods for the FY 2020 Program year, an exchange function for the FY 2019 Program year, and administrative requirements related to review and correction of performance information to be made public. None of these requirements result in any additional information collections or reporting burden associated with the Program.

Additionally, because claims-based measures are calculated based on claims figures that are already submitted to the Medicare program for payment purposes, there is no additional respondent burden associated with data collection or submission for either the SNFRM or SNFPPR measures. Thus, there is no additional reporting burden associated with the SNF VBP Program's measures finalized in this rule.

2. ICRs Regarding the Potentially Preventable 30-Day Post-Discharge Readmission Measure

This rule modifies the Potentially Preventable 30-Day Post-Discharge Readmission Measure by increasing the length of the measurement period and updating the confidential feedback and public reporting dates, as described in section III.D.2.h. Because this is a claims-based measure, no data collection beyond Medicare claims submitted by SNFs for the furnishing of SNF covered services are required for the calculation of this measure. We believe the SNF QRP burden estimate is unaffected by the modifications of this measure as the modifications have no impact on any of the claims-based reported data fields.

3. ICRs Exempt From the PRA

As discussed in this final rule, we are adopting five new measures beginning with the FY 2020 SNF QRP (see section III.D.2.g). The five new measures being finalized are: (1) Changes in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury; (2) Application of the IRF Functional Outcome Measure: Change in Self-Care Score for Medical Rehabilitation Patients (NQF #2633); (3) Application of IRF Functional Outcome Measure: Change in Mobility Score for Medical Rehabilitation Patients (NQF #2634); (4) Application of IRF Functional Outcome Measure: Discharge Self-Care Score for Medical Rehabilitation Patients (NQF #2635); and (5) Application of IRF Functional Outcome Measure: Discharge Mobility Score for Medical Rehabilitation Patients (NQF #2636). The measures must be collected by SNFs and reported to CMS using the Resident Assessment Instrument, Minimum Data Set (MDS).

These measures will be calculated using data elements that are included in the MDS. The data elements are discrete questions and response codes that collect information on a SNF patient's health status, preferences, goals and general administrative information. To view the MDS, with the finalized data elements, we refer to the reader to *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 rule also finalizes that SNFs would be required to report certain standardized resident assessment data beginning with the FY 2019 SNF QRP (see section III.D.2.j.). We are finalizing our definition of the term ''standardized resident assessment data'' as patient assessment questions and response options that are identical in all four PAC assessment instruments, and to which identical standards and definitions apply. The standardized resident assessment data are intended to be shared electronically among PAC providers and will otherwise enable the data to be comparable for various purposes, including the development of cross-setting quality measures and to inform payment models that take into account patient characteristics rather than setting.

Under section 1899B(m) of the Act, the Paperwork Reduction Act does not apply to the specific changes in the collections of information described in this final rule. These changes to the collections of information are being

finalized under section 2(a) of the IMPACT Act, which added new section 1899B to the Act. That section requires SNFs to report standardized resident assessment data, data on quality measures, and data on resource use and other measures. All of this data must, under section 1899B(a)(1)(B) of the Act, be standardized and interoperable to allow for its exchange among PAC providers and other providers and the use by such providers to provide access to longitudinal information to facilitate coordinated care and improved Medicare beneficiary outcomes. Section 1899B(a)(1)(C) of the Act requires us to modify the MDS to allow for the submission of quality measure data and standardized resident assessment data to enable its comparison across SNFs and other providers. We are, however, setting out the burden as a courtesy to advise interested parties of the proposed actions' time and costs and for reference refer to section V.A of this final rule of the regulatory impact analysis (RIA). The requirement and burden will be submitted to OMB for review and approval when the modifications to the MDS have achieved standardization and are no longer exempt from the requirements under section 1899B(m) of the Act.

For the new measure ''Changes in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury'' (NQF #2633) the items used to calculate this measure are already present on the MDS, so the adoption of this measure will not require SNFs to report any new data elements. In addition, we are removing some data elements related to pressure ulcers that have been identified as duplicative. Taking these final policies together, we estimate that there will be a 1.5 minute reduction in clinical staff time needed to report the pressure ulcer measure data. We are also removing 9 additional data elements from the MDS 3.0. The removal of these data elements from the skin integrity section of the MDS provide a reduction in burden with data reporting by SNFs and therefore serve as offsets to the SNF QRP. These removals are: Date of oldest Stage 2 pressure ulcer; three items pertaining to the dimensions of an unhealed pressure ulcer; the most severe tissue type for any pressure ulcer; and four data elements pertaining to healed pressure ulcers. We estimate that the data elements we are removing will reduce overall reporting burden from the assessments, constituting a reduction of an additional 7 minutes of clinical staff time per stay which provide a reduction in burden with data reporting by SNFs. Taken together, we are removing a total of 12 data elements from the skin integrity section of the MDS. Based on the data provided in Table 25 of this final rule, and estimating 2,886,336 discharges from 15,447 SNFs annually, we also estimate that the total cost of reporting these data will reduce overall reporting burden for the assessments from what was proposed constituting a total reduction of 8.5 minutes of clinical staff time per stay or $1,837 per SNF annually, or $28,377,493 for all SNFs annually. We believe that the MDS items will be completed by registered nurses (BLS Occupation Code: 29–1141) at $69.40/hr [55] including overhead and fringe benefits.

For the four functional outcome measures (NQF: #2633, #2634, #2635, and #2636) that we are finalizing in this final rule, we note that although some of the data elements needed to calculate these measures are currently included on the MDS, other data elements need to be added to the MDS. As a result, we estimate that reporting these measures will require an additional 9 minutes of nursing and therapy staff time to report data on admission and 5.5 minutes of nursing and therapy time to report data on discharge, for a total of 14.5 additional minutes per stay. We estimate that the additional MDS items we are finalizing will be completed by Registered Nurses for approximately 7 percent of the time. Occupational Therapists (BLS Occupation Code: 29–1122) at $80.50/hr including overhead and fringe benefits for approximately 41 percent of the time, and Physical Therapists (BLS Occupation Code: 29–1123) at $83.86/hr including overhead and fringe benefits for approximately 52 percent of the time. Individual providers determine the staffing resources necessary. With 2,886,336 discharges from 15,447 SNFs annually, we estimate that the reporting of the four functional outcome measures would impose on SNFs an additional burden of 697,531 total hours (2,886,336 discharges × 14.5 min/60) or 45.16 hours per SNF (697,531 hr/15,447 SNFs). Of the 14.5 minutes per stay, 1 minute of that time is for a Registered Nurse, 3.5 minutes is for an Occupational Therapist, and 4.5 minutes is for a Physical Therapist for a total of 9 minutes are required for admission. For discharge, 2.5 minutes are for an Occupational Therapist, and 3 minutes for a Physical Therapist for a total of 5.5 minutes. For one stay we estimate a cost of $19.69 or, in aggregate, an annual cost of $56,829,551. Per SNF, we estimate an annual cost of $3,679. A summary of these estimates is provided in Table 25.

We are not finalizing our proposal to adopt 1 new standardized resident assessment data elements with respect to SNF admissions and 11 new standardized resident assessment data elements with respect to SNF discharges. This results in a reduction to the burden that we estimated in the proposed rule. We refer readers to the proposed rule (82 FR 21091 through 21092) for a discussion of our burden estimates for these proposals. Our updated estimate is provided in Table 25 (Revised Calculation of Burden), and results in a final estimated burden for the SNF QRP of $28,452,058.

TABLE 25—REVISED CALCULATION OF BURDEN

QRP QM	Data elements	Minutes	Aggregate annual hours all SNFs	Hours per SNF annually	Dollars per stay	Aggregate annual cost all SNFs	Annual cost per SNF
Functional Outcome Measures	18	14.5	697,531	45.16	$ 19.69	$ 56,829,551	$ 3,679
Changes in Skin Integrity	(12)	(8.5)	(408,898)	(26.47)	(9.83)	(28,377,493)	(1,837)
Total	6	6	288,633	18.69	9.86	28,452,058	1,842

[55] U.S. Bureau of Labor Statistics, May 2016 National Occupational Employment and Wage Estimates (see *http://www.bls.gov/oes/current/oes_nat.htm*).

We received the following public comments on our collection of information estimates.

Comment: A few commenters expressed concern about the administrative burden imposed by the SNF QRP, specifically referring to the volume and the pace of data collection that is required by the implementation of the SNF QRP.

Response: We appreciate the commenters' concerns regarding burden due to changes to the SNF QRP as a result of the fulfillment of the requirements of the IMPACT Act. We appreciate the importance of avoiding undue burden on providers and will continue to evaluate and avoid any unnecessary burden associated with the implementation of the SNF QRP. We will continue to work with stakeholders to explore ways to minimize and decrease burden as our mutual goal is to focus on improving patient care. Finally, in response to stakeholders' concerns regarding burden, we have decided not to finalize a number of the proposed standardized resident assessment data elements. This results in a reduction to the burden estimate that appeared in the proposed rule.

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), the Congressional Review Act (5 U.S.C. 804(2)), and Executive Order 13771 on Reducing Regulation and Controlling Regulatory Costs (January 30, 2017). Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). 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.

Executive Order 13771, titled Reducing Regulation and Controlling Regulatory Costs, was issued on January 30, 2017. This final rule is considered an EO 13771 regulatory action. Details on the estimated costs of this rule can be found in the preceding and subsequent analyses.

2. Statement of Need

This final rule updates the FY 2017 SNF prospective payment rates 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 on these issues.

3. Overall Impacts

This final rule sets forth updates of the SNF PPS rates contained in the SNF PPS final rule for FY 2017 (81 FR 51970). Based on the above, we estimate that the aggregate impact is an increase of $370 million in payments to SNFs in FY 2018, resulting from the SNF market basket update to the payment rates, as required by section 1888(e)(5)(B)(iii) of the Act. We would note that this estimate is different from the estimated impact of $390 million provided in the FY 2018 SNF PPS proposed rule (82 FR 21016, 21093), as we relied on an updated SNF baseline spending figure for the final rule which reflect baseline spending from the FY 2018 President's budget, as opposed to that used in the proposed rule which was based on the Mid-session review of the FY 2017 President's budget.

We would note that 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 events that may occur within the assessed impact time period.

In accordance with sections 1888(e)(4)(E) and 1888(e)(5) of the Act, if not for the enactment of section 411(a) of MACRA (as discussed in section III.B.2. of this final rule), we would update the FY 2017 payment rates by a factor equal to the market basket index percentage change adjusted by the MFP adjustment to determine the payment rates for FY 2018. As discussed previously, section 1888(e)(5)(B)(iii) of the Act establishes a special rule for FY 2018 requiring the market basket percentage used to update the federal SNF PPS rates to be equal to 1.0 percent. The impact to Medicare is included in the total column of Table 25. In updating the SNF PPS rates for FY 2018, 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 2018. Accordingly, the analysis of the impact of the annual update that follows only describes the impact of this single year. Furthermore, in accordance with the requirements of the Act, we will publish a rule or notice for each subsequent FY that will provide for an update to the payment rates and include an associated impact analysis.

We estimate the impact for the SNF QRP based on 15,447 SNFs in FY 2016 which had a total of 2,886,336 Medicare covered discharges for Medicare fee for service beneficiaries. This would equate to 288,633 total added hours or 18.69 hours per SNF annually. We anticipate that the additional MDS items we finalized will be completed by Registered Nurses (RN), Occupational Therapists (OT), and/or Physical Therapists (PT), depending on the item. Individual providers determine the staffing resources necessary. We obtained mean hourly wages for these staff from the U.S. Bureau of Labor Statistics' May 2016 National Occupational Employment and Wage Estimates (*https://www.bls.gov/oes/current/oes_nat.htm*), and to account for overhead and fringe benefits, we have doubled the mean hourly wage.

Estimated impacts for the SNF QRP are based on analysis discussed in section III.D.2. of this final rule. For the 8.5 minute reduction in burden associated with the new pressure ulcer measure and the removal of duplicative pressure ulcer data elements and data elements no longer being used, and the additional 14.5 additional minutes of burden for the functional outcome measures, the overall cost associated with finalized changes to the SNF QRP is $28,452,058.

4. Detailed Economic Analysis

The FY 2018 SNF PPS payment impacts appear in Table 26. Using the most recently available data, in this case FY 2016, we apply the current FY 2017

wage index and labor-related share value to the number of payment days to simulate FY 2017 payments. Then, using the same FY 2016 data, we apply the FY 2018 wage index and labor-related share value to simulate FY 2018 payments. We tabulate the resulting payments according to the classifications in Table 26 (for example, facility type, geographic region, facility ownership), and compare the simulated FY 2017 payments to the simulated FY 2018 payments to determine the overall impact. 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 6 rows show the effects on facilities split by hospital-based, freestanding, urban, and rural categories. The next 19 rows show the effects on facilities by urban versus rural status by census region. The last 3 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 2018 payments. The update of 1.0 percent 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 1.0 percent, assuming facilities do not change their care delivery and billing practices in response.

As illustrated in Table 26, 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 Pacific region could experience a 1.5 percent increase in FY 2018 total payments.

TABLE 26—PROJECTED IMPACT TO THE SNF PPS FOR FY 2018

	Number of facilities FY 2018	Update wage data (%)	Total change (%)
Group:			
Total	15,468	0.0	1.0
Urban	11,008	0.1	1.1
Rural	4,460	−0.6	0.4
Hospital-based urban	518	0.2	1.2
Freestanding urban	10,490	0.1	1.1
Hospital-based rural	577	−0.7	0.3
Freestanding rural	3,883	−0.6	0.4
Urban by region:			
New England	791	0.2	1.2
Middle Atlantic	1,487	0.4	1.4
South Atlantic	1,867	−0.2	0.8
East North Central	2,121	0.0	1.0
East South Central	551	−0.6	0.4
West North Central	919	0.7	1.7
West South Central	1,339	0.1	1.1
Mountain	511	−0.2	0.8
Pacific	1,417	0.5	1.5
Outlying	5	−2.0	−1.0
Rural by region:			
New England	137	1.4	2.5
Middle Atlantic	215	−0.5	0.5
South Atlantic	502	−0.7	0.3
East North Central	937	−1.1	−0.1
East South Central	528	−0.9	0.1
West North Central	1,076	−0.4	0.6
West South Central	738	−0.6	0.4
Mountain	228	−0.3	0.7
Pacific	99	0.1	1.1
Ownership:			
Profit	1,045	−0.3	0.7
Non-profit	10,822	0.0	1.0
Government	3,601	0.0	1.0

Note: The Total column includes the 1.0 percent market basket increase required by section 1888(e)(5)(B)(iii) of the Act. Additionally, we found no SNFs in rural outlying areas.

5. Estimated Impacts for the SNF QRP

We estimate the impact for the SNF QRP based on 15,447 SNFs in FY 2016 which had a total of 2,886,336 Medicare covered discharges for Medicare fee for service beneficiaries. This would equate to 288,633 total added hours or 18.69 hours per SNF annually. We anticipate that the additional MDS items we finalized will be completed by Registered Nurses (RN), Occupational Therapists (OT), and/or Physical Therapists (PT), depending on the item. Individual providers determine the staffing resources necessary. We obtained mean hourly wages for these staff from the U.S. Bureau of Labor Statistics' May 2016 National Occupational Employment and Wage Estimates (*https://www.bls.gov/oes/current/oes_nat.htm*), and to account for overhead and fringe benefits, we have doubled the mean hourly wage.

Estimated impacts for the SNF QRP are based on analysis discussed in section III.D.2. of this final rule. For the 8.5 minute reduction in burden associated with the new pressure ulcer measure and the removal of duplicative pressure ulcer data elements and data elements no longer being used, and the additional 14.5 additional minutes of burden for the functional outcome measures, the overall cost associated with finalized changes to the SNF QRP is $28,452,058.

TABLE 27—REVISED CALCULATION OF COST PER QUALITY MEASURE

QRP QM	Data elements	Minutes	Aggregate annual hours all SNFs	Hours per SNF annually	Dollars per stay	Aggregate annual cost all SNFs	Annual cost per SNF
Functional Outcome Measures	18	14.5	697,531	45.16	$19.69	$56,829,551	$3,679
Changes in Skin Integrity	(12)	(8.5)	(408,898)	(26.47)	(9.83)	(28,377,493)	(1,837)
Total	6	6	288,633	18.69	9.86	28,452,058	1,842

6. Estimated Impacts for the SNF VBP Program

Estimated impacts of the FY 2019 SNF VBP Program are based on historical data that appear in Table 28. We modeled SNFs' performance under the Program using SNFRM data from CY 2013 as the baseline period and CY 2015 as the performance period. Additionally, we modeled a logistic exchange function with a payback percentage of 60 percent, as discussed further in the preamble to this final rule.

As illustrated in Table 28, the effects of the SNF VBP Program vary by specific types of providers and by location. For example, we estimate that rural SNFs perform better on the SNFRM, on average, compared to urban SNFs. Similarly, we estimate that non-profit SNFs perform better on the SNFRM compared to for-profit SNFs, and that government-owned SNFs perform better still. We also estimate that smaller SNFs (measured by bed size) tend to perform better, on average, compared to larger SNFs. (We note that the risk-standardized readmission rates presented below are *not* inverted; that is, lower rates represent better performance).

These differences in performance on the SNFRM result in differences in value-based incentive payment percentages computed by the Program. For example, we estimate that, at the proposed 60 percent payback percentage, SNFs in urban areas would receive a 1.161 percent incentive multiplier, on average, in FY 2019, while SNFs in rural areas would receive a slightly higher incentive multiplier of 1.227 percent, on average. Additionally, SNFs in the smallest 25 percent as measured by bed size would receive an incentive multiplier of 1.203 percent, on average, while SNFs in the 2nd quartile as measured by bed size would receive an incentive multiplier of 1.166 percent, on average. We note that the multipliers that we have listed in Table 27 are applied to SNFs' adjusted Federal per diem rates *after* application of the 2 percent reduction to those rates required by statute.

TABLE 28—ESTIMATED FY 2019 SNF VBP PROGRAM IMPACTS

Category	Criterion	Number of facilities	RSRR (mean)	Mean incentive multiplier (60% payback) (%)	Percent of proposed payback
Group	Total	15,746	0.19061	1.218	100.0
	Urban	11116	0.18790	1.161	83.5
	Rural	4,630	0.18293	1.227	16.5
Urban by Region	Total	11,116			
	01=Boston	808	0.18734	1.165	5.978
	02=New York	922	0.18848	1.116	10.590
	03=Philadelphia	1,132	0.18611	1.307	10.295
	04=Atlanta	1,890	0.19291	1.025	12.443
	05=Chicago	2,330	0.18728	1.213	16.248
	06=Dallas	1,379	0.19131	0.920	6.126
	07=Kansas City	666	0.18764	1.109	2.815
	08=Denver	323	0.17831	1.644	2.879
	09=San Francisco	1,325	0.18518	1.174	12.107
	10=Seattle	341	0.17634	1.765	3.983
Rural by Region	Total	4,630			
	01=Boston	145	0.17458	1.648	1.009
	02=New York	94	0.17746	1.435	0.409
	03=Philadelphia	287	0.18145	1.231	1.431
	04=Atlanta	918	0.18633	1.011	3.363
	05=Chicago	1,127	0.18156	1.361	4.662
	06=Dallas	814	0.18676	0.926	1.824
	07=Kansas City	801	0.18459	1.291	1.575
	08=Denver	284	0.17596	1.570	0.883
	09=San Francisco	68	0.16620	1.650	0.706
	10=Seattle	92	0.17488	1.569	0.670
Ownership Type	Total	15,746			

TABLE 28—ESTIMATED FY 2019 SNF VBP PROGRAM IMPACTS—Continued

Category	Criterion	Number of facilities	RSRR (mean)	Mean incentive multiplier (60% payback) (%)	Percent of proposed payback
No. of Beds.	Government	1,096	0.17844	1.240	4.601
	Profit	10,973	0.18864	1.113	71.137
	Non-Profit	3,677	0.18225	1.364	24.260
	1st Quartile:	3,986	0.17935	1.203	13.393
	2nd Quartile:	3,937	0.18646	1.166	19.738
	3rd Quartile:	3,887	0.19009	1.148	26.388
	4th Quartile:	3,938	0.19000	1.204	40.481

7. Regulatory Review Costs

If regulations impose administrative costs on private entities, such as the time needed to read and interpret this final rule, we should estimate the cost associated with regulatory review. Due to the uncertainty involved with accurately quantifying the number of entities that will review the rule, we assume that the total number of unique commenters on the published proposed rule will be the number of reviewers of this final rule. We acknowledge that this assumption may understate or overstate the costs of reviewing this final rule. It is possible that not all commenters reviewed the proposed rule in detail, and it is also possible that some reviewers chose not to comment on the proposed rule. For these reasons we thought that the number of comments received on the proposed rule would be a fair estimate of the number of reviewers of this final rule.

We also recognize that different types of entities are in many cases affected by mutually exclusive sections of this final rule, and therefore for the purposes of our estimate we assume that each reviewer reads approximately 50 percent of the rule.

Using the wage information from the BLS for medical and health service managers (Code 11–9111), we estimate that the cost of reviewing this rule is $105.16 per hour, including overhead and fringe benefits (*https://www.bls.gov/oes/current/oes_nat.htm*) Assuming an average reading speed, we estimate that it would take approximately 4 hours for the staff to review half of this final rule. For each SNF that reviews the rule, the estimated cost is $421 (4 hours × $105.16). Therefore, we estimate that the total cost of reviewing this regulation is $103,987 ($421 × 247 reviewers).

8. Alternatives Considered

As described in this section, we estimate that the aggregate impact for FY 2018 under the SNF PPS is an increase of $370 million in payments to SNFs, resulting from the SNF market basket update to the payment rates, as required by section 1888(e)(5)(B)(iii) of the Act.

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 base 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 this process.

9. Accounting Statement

As required by OMB Circular A–4 (available online at *https://obamawhitehouse.archives.gov/omb/circulars_a004_a-4/*) in Table 29, we have prepared an accounting statement showing the classification of the expenditures associated with the provisions of this final rule for FY 2018. Table 29 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 15,468 SNFs in our database and the cost for the SNF QRP of implementing the IMPACT Act.

TABLE 29—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED EXPENDITURES, FROM THE 2017 SNF PPS FISCAL YEAR TO THE 2018 SNF PPS FISCAL YEAR

Category	Transfers
Annualized Monetized Transfers.	$370 million.*
From Whom To Whom?	Federal Government to SNF Medicare Providers.
FY 2018 Cost to Updating the Quality Reporting Program	
Cost for SNFs to Submit Data for the Quality Reporting Program**.	$29 million.

*The net increase of $370 million in transfer payments is a result of the market basket increase of $370 million.

**Costs associated with the submission of data for the quality reporting program will occur in 2018 and likely continue in the future years.

10. Conclusion

This final rule sets forth updates of the SNF PPS rates contained in the SNF PPS final rule for FY 2017 (81 FR 51970). Based on the above, we estimate the overall estimated payments for SNFs in FY 2018 are projected to increase by $370 million, or 1.0 percent, compared with those in FY 2017. We estimate that in FY 2018 under RUG–IV, SNFs in urban and rural areas will experience, on average, a 1.1 percent increase and 0.4 percent increase, respectively, in estimated payments compared with FY 2017. Providers in the rural New England region will experience the largest estimated increase in payments of approximately 2.5 percent. Providers in the urban Outlying region will experience the largest estimated decrease in payments of 1.0 percent.

Additionally, § 488.314 regarding survey team composition implements section 1819(g)(4) of the Act and provides that States may maintain and

utilize a specialized team that need not include a registered nurse for the investigation of complaints. Section 1919 of the Act contains the same statutory language as applicable to nursing facilities (NFs). Part 488 was originally established under the authority of sections 1819 and 1919 of the Act, which were added by the Omnibus Budget Reconciliation Act of 1987 (OBRA 87, Pub. L. 100–203, enacted on December 22, 1987) and further amendments to OBRA 87 by subsequent 1988, 1989, and 1990 legislation.

Sections 4204(b) and 4214(d) of OBRA 87 pertain to SNFs and NFs, respectively, and provide for a waiver of PRA requirements for the regulations that implement the OBRA 87 requirements. The provisions of OBRA 87 that exempt agency actions to collect information from states or facilities relevant to survey and enforcement activities from the PRA are not time-limited.

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 97 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 *https://www.sba.gov/contracting/getting-started-contractor/make-sure-you-meet-sba-size-standards*). In addition, approximately 23 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 2017 (81 FR 51970). Based on the above, we estimate that the aggregate impact for FY 2018 is an increase of $370 million in payments to SNFs, resulting from the SNF market basket update to the payment rates. While it is projected in Table 26 that most providers will 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 2018 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. In their March 2017 Report to Congress (available at *http://medpac.gov/docs/default-source/reports/mar17_medpac_ch8.pdf*), MedPAC states that Medicare covers approximately 11 percent of total patient days in freestanding facilities and 21 percent of facility revenue (March 2017 MedPAC Report to Congress, 202). 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 26. As indicated in Table 25, the effect on facilities is projected to be an aggregate positive impact of 1.0 percent for FY 2018. 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 will not have a significant impact on a substantial number of small entities for FY 2018.

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 affects 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 will be similar to the impact on SNF providers overall. Moreover, as noted in previous SNF PPS final rules (most recently, the one for FY 2017 (81 FR 51970)), the category of small rural hospitals is included within the analysis of the impact of this final rule on small entities in general. As indicated in Table 25, the effect on facilities for FY 2018 is projected to be an aggregate positive impact of 1.0 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 does not have a significant impact on a substantial number of small rural hospitals for FY 2018.

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 2017, that threshold is approximately $148 million. This final rule will impose no mandates on state, local, or tribal governments or on the private sector.

D. Federalism Analysis

Executive Order 13132 establishes certain requirements that an agency must meet when it issues a final rule that imposes substantial direct requirement costs on state and local governments, preempts state law, or otherwise has federalism implications. This final rule has no substantial direct effect on state and local governments, preempt state law, or otherwise have federalism implications.

E. Congressional Review Act

This regulation 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.

List of Subjects

42 CFR Part 409

Health facilities, Medicare.

42 CFR Part 411

Diseases, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 413

Health facilities, Diseases, Medicare, Reporting and recordkeeping requirements.

42 CFR part 424

Emergency medical services, Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 488

Administrative practice and procedure, Health facilities, Medicare, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services amends 42 CFR chapter IV as set forth below:

PART 409—HOSPITAL INSURANCE BENEFITS

■ 1. The authority citation for part 409 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

■ 2. Section 409.30 is amended by revising the introductory text to read as follows:

§ 409.30 Basic requirements.

Posthospital SNF care, including SNF-type care furnished in a hospital or CAH that has a swing-bed approval, is covered only if the beneficiary meets the requirements of this section and only for days when he or she needs and receives care of the level described in § 409.31. A beneficiary in an SNF is also considered to meet the level of care requirements of § 409.31 up to and including the assessment reference date for the 5-day assessment prescribed in § 413.343(b) of this chapter, when correctly assigned one of the case-mix classifiers that CMS designates for this purpose as representing the required level of care. For the purposes of this section, the assessment reference date is defined in accordance with § 483.315(d) of this chapter, and must occur no later than the eighth day of posthospital SNF care.

* * * * *

PART 411—EXCLUSIONS FROM MEDICARE AND LIMITATIONS ON MEDICARE PAYMENT

■ 3. The authority citation for part 411 continues to read as follows:

Authority: Secs. 1102, 1860D–1 through 1860D–42, 1871, and 1877 of the Social Security Act (42 U.S.C. 1302, 1395w–101 through 1395w–152, 1395hh, and 1395nn).

■ 4. Section 411.15 is amended by revising paragraph (p)(3)(iii) to read as follows:

§ 411.15 Particular services excluded from coverage.

* * * * *

(p) * * *

(3) * * *

(iii) The beneficiary receives outpatient services from a Medicare-participating hospital or CAH (but only for those services that CMS designates as being beyond the general scope of SNF comprehensive care plans, as required under § 483.21(b) of this chapter); or

* * * * *

PART 413—PRINCIPLES OF REASONABLE COST REIMBURSEMENT; PAYMENT FOR END–STAGE RENAL DISEASE SERVICES; PROSPECTIVELY DETERMINED PAYMENT RATES FOR SKILLED NURSING FACILITIES; PAYMENT FOR ACUTE KIDNEY INJURY DIALYSIS

■ 5. The authority citation for part 413 continues to read as follows:

Authority: 42 U.S.C. 1302; 42 U.S.C. 1395d(d); 42 U.S.C. 1395f(b); 42 U.S.C. 1395g; 42 U.S.C. 1395l(a), (i), and (n); 42 U.S.C. 1395x(v); 42 U.S.C. 1395hh; 42 U.S.C. 1395rr; 42 U.S.C. 1395tt; 42 U.S.C. 1395ww; sec. 124 of Public Law 106–113, 113 Stat. 1501A–332; sec. 3201 of Public Law 112–96, 126 Stat. 156; sec. 632 of Public Law 112–240, 126 Stat. 2354; sec. 217 of Public Law 113–93, 129 Stat. 1040; sec. 204 of Public Law 113–295, 128 Stat. 4010; and sec. 808 of Public Law 114–27, 129 Stat. 362.

■ 6. The heading for part 413 is revised to read as set forth above.

■ 7. Section 413.333 is amended by revising the definition of ''Resident classification system'' to read as follows:

§ 413.333 Definitions.

* * * * *

Resident classification system means a system for classifying SNF residents into mutually exclusive groups based on clinical, functional, and resource-based criteria. For purposes of this subpart, this term refers to the current version of the resident classification system, as set forth in the annual publication of Federal prospective payment rates described in § 413.345.

* * * * *

■ 8. Section 413.337 is amended by adding paragraph (d)(4) to read as follows:

§ 413.337 Methodology for calculating the prospective payment rates.

* * * * *

(d) * * *

(4) *Penalty for failure to report quality data.* For fiscal year 2018 and subsequent fiscal years—

(i) In the case of a SNF that does not meet the requirements in § 413.360, for a fiscal year, the SNF market basket index percentage change for the fiscal year (as specified in paragraph (d)(1)(v) of this section, as modified by any applicable forecast error adjustment under paragraph (d)(2) of this section, reduced by the MFP adjustment specified in paragraph (d)(3) of this section, and as specified for FY 2018 in section 1888(e)(5)(B)(iii) of the Act), is further reduced by 2.0 percentage points.

(ii) The application of the 2.0 percentage point reduction specified in paragraph (d)(4)(i) of this section to the SNF market basket index percentage change may result in such percentage being less than zero for a fiscal year, and may result in payment rates for that fiscal year being less than such payment rates for the preceding fiscal year.

(iii) Any 2.0 percentage point reduction applied pursuant to paragraph (d)(4)(i) of this section will apply only to the fiscal year involved and will not be taken into account in computing the payment amount for a subsequent fiscal year.

* * * * *

■ 9. Section 413.338 is added to read as follows:

§ 413.338 Skilled nursing facility value-based purchasing.

(a) *Definitions.* As used in this section:

(1) *Achievement threshold (or achievement performance standard)* means the 25th percentile of SNF performance on the SNF readmission measure during the baseline period for a fiscal year.

(2) *Adjusted Federal per diem rate* means the payment made to SNFs under the skilled nursing facility prospective payment system (as described under section 1888(e)(4)(G) of the Act).

(3) *Applicable percent* means for FY 2019 and subsequent fiscal years, 2.0 percent.

(4) *Baseline period* means the time period used to calculate the achievement threshold, benchmark and improvement threshold that apply for a fiscal year.

(5) *Benchmark* means, for a fiscal year, the arithmetic mean of the top decile of SNF performance on the SNF readmission measure during the baseline period for that fiscal year.

(6) *Logistic exchange function* means the function used to translate a SNF's performance score on the SNF readmission measure into a value-based incentive payment percentage.

(7) *Improvement threshold (or improvement performance standard)* means an individual SNF's performance on the SNF readmission measure during the applicable baseline period.

(8) *Performance period* means the time period during which performance on the SNF readmission measure is calculated for a fiscal year.

(9) *Performance standards* are the levels of performance that SNFs must meet or exceed to earn points under the SNF VBP Program for a fiscal year, and are announced no later than 60 days prior to the start of the performance period that applies to the SNF readmission measure for that fiscal year.

(10) *Ranking* means the ordering of SNFs based on each SNF's performance score under the SNF VBP Program for a fiscal year.

(11) *SNF readmission measure* means, for a fiscal year, the all-cause all-condition hospital readmission measure (SNFRM) or the all-condition risk-adjusted potentially preventable hospital readmission rate (SNFPPR) specified by CMS for application in the SNF Value-Based Purchasing Program.

(12) *Performance score* means the numeric score ranging from 0 to 100 awarded to each SNF based on its performance under the SNF VBP Program for a fiscal year.

(13) *SNF Value-Based Purchasing (VBP) Program* means the program required under section 1888(h) of the Social Security Act.

(14) *Value-based incentive payment amount* is the portion of a SNF's adjusted Federal per diem rate that is attributable to the SNF VBP Program.

(15) *Value-based incentive payment adjustment factor* is the number that will be multiplied by the adjusted Federal per diem rate for services furnished by a SNF during a fiscal year, based on its performance score for that fiscal year, and after such rate is reduced by the applicable percent.

(b) *Applicability of the SNF VBP Program.* The SNF VBP Program applies to SNFs, including facilities described in section 1888(e)(7)(B).

(c) *Process for reducing the adjusted Federal per diem rate and applying the value-based incentive payment adjustment factor under the SNF VBP Program*—(1) *General.* CMS will make value-based incentive payments to each SNF based on its performance score for a fiscal year under the SNF VBP Program under the requirements and conditions specified in this paragraph.

(2) *Value-based incentive payment amount*—(i) *Total amount available for a fiscal year.* The total amount available for value-based incentive payments for a fiscal year is equal to 60 percent of the total amount of the reduction to the adjusted SNF PPS payments for that fiscal year, as estimated by CMS.

(ii) *Calculation of the value-based incentive payment amount.* The value-based incentive payment amount is calculated by multiplying the adjusted Federal per diem rate by the value-based incentive payment adjustment factor, after the adjusted Federal per diem rate has been reduced by the applicable percent.

(iii) *Calculation of the value-based incentive payment adjustment factor.* The value-based incentive payment adjustment factor is calculated by estimating Medicare spending under the skilled nursing facility prospective payment system to estimate the total amount available for value-based incentive payments, ordering SNFs by their SNF performance scores, then assigning an adjustment factor value for each performance score subject to the limitations set by the exchange function.

(iv) *Reporting of adjustment to SNF payments.* CMS will inform each SNF of the value-based incentive payment adjustment factor that will be applied to its adjusted Federal per diem rate for services furnished during a fiscal year at least 60 days prior to the start of that fiscal year.

(d) *Performance scoring under the SNF VBP Program.* (1) CMS will award points to SNFs based on their performance on the SNF readmission measure applicable to a fiscal year during the performance period applicable to that fiscal year as follows:

(i) CMS will award from 1 to 99 points for achievement to each SNF whose performance meets or exceeds the achievement threshold but is less than the benchmark.

(ii) CMS will award from 0 to 90 points for improvement to each SNF whose performance exceeds the improvement threshold but is less than the benchmark.

(iii) CMS will award 100 points to a SNF whose performance meets or exceeds the benchmark.

(2) The highest of the SNF's achievement, improvement and benchmark score will be the SNF's performance score for the fiscal year.

(e) *Confidential feedback reports and public reporting.* (1) Beginning October 1, 2016, CMS will provide quarterly confidential feedback reports to SNFs on their performance on the SNF readmission measure. SNFs will have the opportunity to review and submit corrections for this data by March 31st following the date that CMS provides the reports. Any such correction requests must be accompanied by appropriate evidence showing the basis for the correction.

(2) Beginning not later than 60 days prior to each fiscal year, CMS will provide SNF performance score reports to SNFs on their performance under the SNF VBP Program for a fiscal year. SNFs will have the opportunity to review and submit corrections to their SNF performance scores and ranking contained in these reports for 30 days following the date that CMS provides the reports. Any such correction requests must be accompanied by appropriate evidence showing the basis for the correction.

(3) CMS will publicly report the information described in paragraphs (e)(1) and (2) of this section on the Nursing Home Compare Web site.

(f) *Limitations on review.* There is no administrative or judicial review of the following:

(1) The methodology used to determine the value-based incentive payment percentage and the amount of the value-based incentive payment under section 1888(h)(5) of the Act.

(2) The determination of the amount of funding available for value-based incentive payments under section 1888(h)(5)(C)(ii)(III) of the Act and the payment reduction under section 1888(h)(6) of the Act.

(3) The establishment of the performance standards under section 1888(h)(3) of the Act and the performance period.

(4) The methodology developed under section 1888(h)(4) of the Act that is used to calculate SNF performance scores and the calculation of such scores.

(5) The ranking determinations under section 1888(h)(4)(B) of the Act.

■ 10. Section 413.345 is revised to read as follows:

§ 413.345 Publication of Federal prospective payment rates.

CMS publishes information pertaining to each update of the Federal payment rates in the **Federal Register**. This information includes the standardized Federal rates, the resident classification system that provides the basis for case-mix adjustment, and the factors to be applied in making the area wage adjustment. This information is published before May 1 for the fiscal year 1998 and before August 1 for the fiscal years 1999 and after.

■ 11. Section 413.360 is added to subpart J to read as follows:

§ 413.360 Requirements under the Skilled Nursing Facility (SNF) Quality Reporting Program (QRP).

(a) *Participation start date.* Beginning with the FY 2018 program year, a SNF must begin reporting data in accordance with paragraph (b) of this section 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, which designates the SNF as operating in the Certification and Survey Provider Enhanced Reports (CASPER) system. For purposes of this section, a program

year is the fiscal year in which the market basket percentage described in § 413.337(d) is reduced by two percentage points if the SNF does not report data in accordance with paragraph (b) of this section.

(b) *Data submission requirement.* (1) Except as provided in paragraph (c) of this section, and for a program year, SNFs must submit to CMS data on measures specified under sections 1899B(c)(1) and 1899B(d)(1) of the Social Security Act and standardized resident assessment data in accordance with section 1899B(b)(1) of the Social Security Act, in the form and manner, and at a time, specified by CMS.

(2) CMS will consider a SNF to have complied with paragraph (b)(1) of this section for a program year if the SNF reports: 100 percent of the required data elements on at least 80 percent of the MDS assessments submitted for that program year.

(c) *Exception and extension requests.* (1) A SNF may request and CMS may grant exceptions or extensions to the reporting requirements under paragraph (b) of this section for one or more quarters, when there are certain extraordinary circumstances beyond the control of the SNF.

(2) A SNF may request an exception or extension within 90 days of the date that the extraordinary circumstances occurred by sending an email to *SNFQRPReconsiderations@cms.hhs.gov* that contains all of the following information:

(i) SNF CMS Certification Number (CCN).

(ii) SNF Business Name.

(iii) SNF Business Address.

(iv) CEO or CEO-designated personnel contact information including name, telephone number, title, email address, and mailing address. (The address must be a physical address, not a post office box.)

(v) SNF's reason for requesting the exception or extension.

(vi) Evidence of the impact of extraordinary circumstances, including, but not limited to, photographs, newspaper, and other media articles.

(vii) Date when the SNF believes it will be able to again submit SNF QRP data and a justification for the proposed date.

(3) Except as provided in paragraph (c)(4) of this section, CMS will not consider an exception or extension request unless the SNF requesting such exception or extension has complied fully with the requirements in this paragraph (c).

(4) CMS may grant exceptions or extensions to SNFs without a request if it determines that one or more of the following has occurred:

(i) An extraordinary circumstance affects an entire region or locale.

(ii) A systemic problem with one of CMS's data collection systems directly affected the ability of a SNF to submit data in accordance with paragraph (b) of this section.

(d) *Reconsideration.* (1) SNFs that do not meet the requirement in paragraph (b) of this section for a program year will receive a letter of non-compliance through the Quality Improvement and Evaluation System Assessment Submission and Processing (QIES–ASAP) system, as well as through the United States Postal Service. A SNF may request reconsideration no later than 30 calendar days after the date identified on the letter of non-compliance.

(2) Reconsideration requests must be submitted to CMS by sending an email to *SNFQRPReconsiderations@cms.hhs.gov* containing all of the following information:

(i) SNF CCN.

(ii) SNF Business Name.

(iii) SNF Business Address.

(iv) CEO or CEO-designated personnel contact information including name, telephone number, title, email address, and mailing address. (The address must be a physical address, not a post office box.)

(v) CMS identified reason(s) for non-compliance stated in the non-compliance letter.

(vi) Reason(s) for requesting reconsideration, including all supporting documentation.

(3) CMS will not consider a reconsideration request unless the SNF has complied fully with the requirements in paragraph (d)(2) of this section.

(4) CMS will make a decision on the request for reconsideration and provide notice of the decision to the SNF through the QIES–ASAP system and via letter sent through the United States Postal Service.

(e) *Appeals.* A SNF that is dissatisfied with CMS' decision on a request for reconsideration may file an appeal with the Provider Reimbursement Review Board (PRRB) under 42 CFR part 405, subpart R.

PART 424—CONDITIONS FOR MEDICARE PAYMENT

■ 12. The authority citation for part 424 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

§ 424.20 [Amended]

■ 13. In § 424.20—

■ a. Amend paragraph (a)(1)(ii) by removing the phrase ''to one of the Resource Utilization Groups designated'' and adding in its place the phrase ''one of the case-mix classifiers that CMS designates''; and

■ b. Amend paragraph (e)(2)(ii)(B)(*2*) by removing the reference ''§ 483.40(e)'' and adding in its place the reference ''§ 483.30(e)''.

PART 488—SURVEY, CERTIFICATION, AND ENFORCEMENT PROCEDURES

■ 14. The authority citation for part 488 continues to read as follows:

Authority: Secs. 1102, 1128l, 1864, 1865, 1871 and 1875 of the Social Security Act, unless otherwise noted (42 U.S.C 1302, 1320a–7j, 1395aa, 1395bb, 1395hh) and 1395ll.

■ 15. Section 488.30(a) is amended by revising the definition of ''Complaint surveys'' to read as follows:

§ 488.30 Revisit user fee for revisit surveys.

(a) * * *

Complaint surveys means those surveys conducted on the basis of a substantial allegation of noncompliance, as defined in § 488.1. The requirements of sections 1819(g)(4) and 1919(g)(4) of the Social Security Act and § 488.332 apply to complaint surveys.

* * * * *

■ 16. Section 488.301 is amended by revising the definition of ''Abbreviated standard survey'' to read as follows:

§ 488.301 Definitions.

* * * * *

Abbreviated standard survey means a survey other than a standard survey that gathers information primarily through resident-centered techniques on facility compliance with the requirements for participation. An abbreviated standard survey may be premised on complaints received; a change of ownership, management, or director of nursing; or other indicators of specific concern. Abbreviated standard surveys conducted to investigate a complaint or to conduct on-site monitoring to verify compliance with participation requirements are subject to the requirements of § 488.332. Other premises for abbreviated standard surveys would follow the requirements of § 488.314.

* * * * *

■ 17. In § 488.308—

■ a. Redesignate paragraphs (e)(2) and (3) as paragraphs (f)(1) and (2);

■ b. Reserve paragraph (e)(2);

■ c. Add a paragraph heading for new paragraph (f); and
■ d. Revise newly redesignated paragraph (f)(1) introductory text.

The addition and revision read as follows:

§ 488.308 Survey frequency.

* * * * *

(e) * * *

(2) [Reserved]

* * * * *

(f) *Investigation of complaints.* (1) The survey agency must review all complaint allegations and conduct a standard or an abbreviated survey to investigate complaints of violations of requirements by SNFs and NFs if its review of the allegation concludes that—

* * * * *

■ 18. Section 488.314 is amended by revising paragraph (a)(1) to read as follows:

§ 488.314 Survey teams.

(a) * * *

(1) Surveys under sections 1819(g)(2) and 1919(g)(2) of the Social Security Act must be conducted by an interdisciplinary team of professionals, which must include a registered nurse.

* * * * *

Dated: July 26, 2017.

Seema Verma,

Administrator, Centers for Medicare & Medicaid Services.

Dated: July 27, 2017.

Thomas E. Price,

Secretary, Department of Health and Human Services.

[FR Doc. 2017–16256 Filed 7–31–17; 4:15 pm]

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Part III

Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Part 418

Medicare Program; FY 2018 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–1675–F]

RIN 0938–AT00

Medicare Program; FY 2018 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) 2018. Additionally, this rule includes new quality measures and provides an update on the hospice quality reporting program.

DATES: These regulations are effective on October 1, 2017.

FOR FURTHER INFORMATION CONTACT: Debra Dean-Whittaker, (410) 786–0848 for questions regarding the CAHPS® Hospice Survey.

Cindy Massuda, (410) 786–0652 for questions regarding the hospice quality reporting program.

For general questions about hospice payment policy, please send your inquiry via email to: *hospicepolicy@cms.hhs.gov*.

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
CASPER Certification and Survey Provider Enhanced Reports
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
CMS Centers for Medicare & Medicaid Services
COPD Chronic Obstructive Pulmonary Disease
CoPs Conditions of Participation
CPI–U Consumer Price Index-Urban Consumers
CVA Cerebral Vascular Accident
CWF Common Working File
CY Calendar Year
DME Durable Medical Equipment
DRG Diagnostic Related Group
FEHC Family Evaluation of Hospice Care
FR Federal Register
FY Fiscal Year
GAO Government Accountability Office
GIP General Inpatient Care
HCFA Healthcare Financing Administration
HEART Hospice Evaluation & Assessment Reporting Tool

HHS Health and Human Services
HIS Hospice Item Set
HQRP Hospice Quality Reporting Program
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
IPPS Inpatient Prospective Payment System
IRC Inpatient Respite Care
LCD Local Coverage Determination
MAC Medicare Administrative Contractor
MACRA Medicare Access and CHIP Reauthorization Act of 2015
MAP Measure Applications Partnership
MedPAC Medicare Payment Advisory Commission
MFP Multifactor Productivity
MLN Medicare Learning Network
MSA Metropolitan Statistical Area
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
PRA Paperwork Reduction Act of 1995
PRRB Provider Reimbursement Review Board
PS&R Provider Statistical and Reimbursement Report
Pub. L. Public Law
POC Plan of Care
QAPI Quality Assessment and Performance Improvement
QIO Quality Improvement Organization
QM Quality Measure
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) 2018, as required under section 1814(i) of the Social Security Act (the Act). This rule also discusses 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. In accordance with section 1814(i)(5)(A) of the Act, hospices that fail to meet quality reporting requirements receive a 2 percentage point reduction to their payments.

B. Summary of the Major Provisions

Section III.B.1 of this final rule updates the hospice wage index with updated wage data and makes the application of the updated wage data budget neutral for all four levels of hospice care. In section III.B.2 of this final rule, we discuss the FY 2018 hospice payment update percentage of 1.0 percent. Sections III.B.3 and III.B.4 of this final rule update the hospice payment rates and hospice cap amount for FY 2018 by the hospice payment update percentage discussed in section III.B.2 of this final rule.

In section III.C of this final rule, we discuss comments on the appropriate source(s) of the required clinical information for certification of a medical prognosis of a life expectancy of 6 months or less.

Finally, in section III.D of this final rule, we discuss updates to HQRP, including changes to the Consumer Assessment of Healthcare Providers and Systems (CAHPS)® Hospice Survey measures as well as the possibility of utilizing a new assessment instrument to collect quality data. We also discuss the enhancements to the current Hospice Item Set (HIS) data collection instrument to be more in line with other post-acute care settings. The new data collection instrument would be a comprehensive patient assessment instrument, rather than the current chart abstraction tool. Finally, we discuss our plans for sharing HQRP data publicly later in calendar year (CY) 2017, as well as plans to provide public reporting via a Compare Site in CY 2017 and future years.

C. Summary of Impacts

The overall economic impact of this final rule is estimated to be $180 million in increased payments to hospices during FY 2018.

II. Background

A. Hospice Care

Hospice care is a comprehensive, holistic approach to treatment that recognizes that the impending death of an individual, upon his or her choice, 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 a collaboration 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/caregiver-centered care for those who are terminally ill.

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. For more information, see ''Medicare and Medicaid Programs: 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 and caregivers through early identification and management of pain and other issues associated with a life limiting condition. The hospice interdisciplinary group works with the beneficiary, family, and caregivers to develop a coordinated, comprehensive care plan; reduce unnecessary diagnostics or ineffective therapies; and maintain ongoing communication with individuals and their families about changes in their condition. The beneficiary's 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 related to the underlying condition(s), as bodily systems are interdependent. In the 2008 Hospice Conditions of Participation final rule, we stated that ''the [hospice] medical director 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 regulations at § 418.22(b)(3) require that the certification and recertification forms include a brief narrative explanation of the clinical findings that support a life expectancy of 6 months or less.

While the goal of hospice care is to allow the beneficiary to remain in his or her home, circumstances during the end of life may necessitate short-term inpatient admission to a hospital, skilled nursing facility (SNF), or hospice facility for necessary pain control or acute or chronic symptom management that cannot be managed in any other setting. These acute hospice care services ensure that any new or worsening symptoms are intensively addressed so that the beneficiary can return to his or her home. Limited, short-term, intermittent, inpatient respite care (IRC) is also available because of the absence or need for relief of the family or other caregivers. Additionally, an individual can receive continuous home care (CHC) during a period of crisis in which an individual requires continuous care to achieve palliation or management of acute medical symptoms so that the individual can remain at home. Continuous home care may be covered 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. Additionally, they must 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/ocr/civilrights*.

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 entitled ''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 well as, care for interventions to manage pain and symptoms, as described in the beneficiary's plan of care. 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 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 home from an institutional 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.

[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.

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, the 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). 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 community based, holistic, comprehensive, and compassionate end-of-life care.

Before the Medicare hospice benefit was established, the Congress requested a demonstration project to test the feasibility of covering hospice care under Medicare.[3] 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 asupportive 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 thedeath 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. Most 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 (IRC), and general inpatient care (GIP)), 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 and items 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

[3] Greer, D., Mor, V., Sherwood, S. (1983) National hospice study analysis plan. Journal of Chronic Diseases, Vol 36, 11, 737–780. *https://doi.org/10.1016/0021-9681(83)90069-3.*

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, were subject to either a budget neutrality adjustment or application of the wage index floor. Wage index values of 0.8 or greater were 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, and 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 that fail to report quality data will have their market basket percentage increase 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, the Congress included an aggregate cap on hospice payments, which limits the total aggregate payments any individual hospice can receive in a year. The 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, within certain limits. We allowed existing hospices the option of having their cap calculated via the original streamlined methodology, also within certain limits. 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 payments for the cap year exceed 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 of 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. Over time, we have 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 as of 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 Wage Index and Payment 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 Wage Index and Payment 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 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 fiscal year 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.

10. FY 2017 Hospice Wage Index and Payment Rate Update Final Rule

In the FY 2017 Hospice Wage Index and Payment Rate Update final rule, we finalized several new policies and requirements related to the HQRP. First, we codified our policy that if the National Quality Forum (NQF) makes non-substantive changes to specifications for HQRP measures as part of the NQF's re-endorsement process, we will continue to utilize the measure in its new endorsed status, without going through new notice-and-comment rulemaking (81 FR 52160). We will continue to use rulemaking to adopt substantive updates made by the NQF to the endorsed measures we have adopted for the HQRP; determinations about what constitutes a substantive versus non-substantive change will be made on a measure-by-measure basis. Second, we finalized two new quality measures for the HQRP 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 (81 FR 52173). The data collection mechanism for both of these measures is the HIS, and the measures are effective April 1, 2017. Regarding the CAHPS® Hospice Survey, we finalized a policy that hospices that receive their CMS Certification Number (CCN) after January 1, 2017 for the FY 2019 Annual Payment Update (APU) and January 1, 2018 for the FY 2020 APU will be exempted from the Hospice CAHPS® requirements due to newness (81 FR 52182). The exemption is

determined by CMS and is for 1 year only.

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 2016. Similarly, Medicare hospice expenditures have risen from $2.8 billion in FY 2000 to approximately $16.5 billion in FY 2016. 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 2016 in neurologically-based diagnoses, including diagnoses of Alzheimer's disease. Additionally, there have 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 2016, the most common hospice principal diagnoses were Alzheimer's disease, Heart Failure, Chronic Obstructive Pulmonary Disease, Lung Cancer, and Senile Degeneration of the Brain, which constituted approximately 30 percent of all claims-reported principal diagnosis codes reported in FY 2016 (see Table 2).

TABLE 2—THE TOP TWENTY PRINCIPAL HOSPICE DIAGNOSES, FY 2002, FY 2007, FY 2013, FY 2016

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
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 Behavior. 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

TABLE 2—THE TOP TWENTY PRINCIPAL HOSPICE DIAGNOSES, FY 2002, FY 2007, FY 2013, FY 2016—Continued

Rank	ICD–9/Reported principal diagnosis		Count	Percentage
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 2016				
1	G30.9	Alzheimer's disease, unspecified	162,845	11
2	I50.9	Heart failure, unspecified	84,088	6
3	J44.9	Chronic obstructive pulmonary disease, unspecified	74,131	5
4	C34.90	Malignant Neoplasm Of Unsp Part Of Unsp Bronchus Or Lung	57,077	4
5	G31.1	Senile degeneration of brain, not elsewhere classified	55,305	4
6	G20	Parkinson's disease	37,245	2
7	I25.10	Atherosclerotic heart disease of native coronary art without angina pectoris	33,647	2
8	J44.1	Chronic obstructive pulmonary disease with (acute) exacerbation	32,851	2
9	G30.1	Alzheimer's disease with late onset	29,223	2
10	I67.2	Cerebral atherosclerosis	27,629	2
11	C61	Malignant neoplasm of prostate	24,576	2
12	N18.6	End stage renal disease	22,261	1
13	C18.9	Malignant neoplasm of colon, unspecified	22,203	1
14	I51.9	Heart disease, unspecified	21,868	1
15	C25.9	Malignant neoplasm of pancreas, unspecified	20,400	1
16	I63.9	Cerebral infarction, unspecified	18,546	1
17	I67.9	Cerebrovascular disease, unspecified	14,879	1
18	C50.919	Malignant neoplasm of unspecified site of unspecified female breast	14,022	1
19	A41.9	Sepsis, unspecified organism	12,723	1
20	I50.22	Chronic systolic (congestive) heart failure	12,083	1

Note(s): The frequencies shown represent beneficiaries that had a least one claim with the specific ICD–9–CM/ICD–10 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 2016 hospice claims data from the CCW, accessed and merged with ICD–10 codes on January 9, 2017.

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 2016 hospice claims show that 100 percent of hospices reported one diagnosis, 86 percent submitted at least two diagnoses, and 77 percent included at least three diagnoses.

III. Provisions of the Final Rule

On May 3, 2017, we published the FY 2018 Hospice Wage Index and Payment Rate Update and Hospice Quality Reporting Requirements proposed rule in the **Federal Register** (82 FR 20750 through 20792) and provided a 60 day comment period. In that proposed rule, we proposed to update the hospice wage index, payment rates, and cap amount for fiscal year (FY) 2018. In addition, we

proposed changes to the hospice quality reporting program. 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. We received approximately 89 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 2018 Hospice Payment Rate Update and Hospice Quality Reporting Requirements. Comments related to the paperwork burden are addressed in section IV ''Collection of Information Requirements'' of this final rule. Comments related to the impact analysis are addressed in section V ''Regulatory Impact Analysis'' of this final rule.

A. Monitoring for Potential Impacts—Affordable Care Act Hospice Reform

In the FY 2018 Hospice Wage Index and Payment Rate Update proposed rule (82 FR 20750), we provided a summary of analysis conducted on hospice length of stay, live discharge rates, skilled visits in the last days of life, and non-hospice spending. Additionally, we discussed initial analyses of data from recently revised cost reports. 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.

The comments and our responses are set forth below.

Comment: Many commenters expressed continued support for our plans to monitor the impact of hospice payment reform and suggested the use of monitoring results in order to better target program integrity efforts. Commenters suggested CMS ensure hospices with a high number of live discharges receive the appropriate training on hospice eligibility requirements, which may help reduce their number of live discharges to a threshold more aligned with other hospices with similar demographics. With regards to skilled visits during the last days of life, a few commenters stated that hospices continue to 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. With regards to the initial analysis of newly-revised cost report data, several commenters encouraged CMS to approach further analysis in a deliberate fashion, taking into account the ''newness'' of the data collected, further educate providers on appropriate completion of the cost report forms, and audit cost reports before moving forward with any further research. Several commenters suggested that CMS take action to educate other Medicare provider types to increase understanding of benefits coverage and claims processing after a beneficiary has elected hospice and encouraged Medicare systems changes that could shorten the time frame for updates to the beneficiary's status in all systems. Several commenters recommended that CMS make more data available to the hospice providers and other stakeholders, especially with regards to Part D billing, and consider clarifying the responsibilities for prescription medications to decrease Part D non-hospice spending.

Response: We appreciate these comments on the ongoing analysis presented and we will continue to monitor hospice trends and vulnerabilities within the hospice benefit, while also investigating the means by which we can educate the provider community regarding the hospice benefit and appropriate billing practices. We will also consider these suggestions for future monitoring efforts and for potential policy or payment refinements. We are currently working on a process to allow NOEs to be submitted via electronic data interchange while simultaneously working on a redesign of hospice benefit period data in our systems. Allowing NOEs to be submitted via an electronic data interchange and the hospice benefit period data redesign should help with more timely beneficiary status updates in the Medicare systems.

B. FY 2018 Hospice Wage Index and Rate Update

1. FY 2018 Hospice Wage Index

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 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 2018, the hospice wage index will be based on the FY 2017 hospital pre-floor, pre-reclassified 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 IRC.

There exist 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 2008 Hospice Wage Index final rule (72 FR 50214), we implemented a methodology to update the hospice wage index for such areas. In cases where there was a rural area without rural hospital wage data, we use the average pre-floor, pre-reclassified hospital wage index data from all contiguous Core-Based Statistical Areas (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, 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 FY 2018, we will continue to use the most recent pre-floor, pre-reclassified hospital wage index value available for Puerto Rico, which is 0.4047.

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. For FY 2018, the only CBSA without a hospital from which hospital wage data can be derived is 25980, Hinesville-Fort Stewart, Georgia.

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 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.

On February 28, 2013, OMB issued OMB Bulletin No. 13–01, announcing revisions to the delineation of MSAs, Micropolitan Statistical Areas, and Combines Statistical Areas, and guidance on uses of the delineation in these areas. In the FY 2016 Hospice Wage Index and Payment Rate Update final rule (80 FR 47178), we adopted the OMB's new area delineations using a 1-year transition. Also, in the FY 2016 Hospice Wage Index and Payment Rate Update final rule, we stated that beginning October 1, 2016, the wage index for all hospice payments would be fully based on the new OMB delineations. The most recent bulletin (No. 15–01) concerning the revised delineations was published by the OMB on July 15, 2015.

A summary of the comments we received regarding the wage index and our responses to those comments appears below.

Comment: Several commenters expressed concern that hospices in Montgomery County and Frederick County, Maryland, which are included in CBSA 43524 (Silver Spring-Frederick-Rockville, MD), are reimbursed at a lower rate than hospices in the greater Washington DC area that are included in CBSA 47894 (Washington-Arlington-Alexandria, DC-VA-MD-WV). The commenters request that CMS reconsider CBSA 43524 (Silver Spring-Frederick-Rockville, MD).

Response: We refer readers of this final rule to the FY 2016 Hospice Wage Index and Payment Rate Update (80 FR 47179 through 47180) wherein we provided a detailed response to this comment.

Comment: A commenter stated that another complicating factor related to the wage index value for CBSA 43524 (Silver Spring-Frederick-Rockville, MD) is the Maryland Federal Waiver and global budget. In all other states, cost reports drive reimbursement for hospitals and accurate reporting of wages is key to reimbursement rates. The commenter believes that since the data on cost reports does not relate to their reimbursement, hospitals in Maryland have no incentive to report their wages accurately. The commenter asserts that there are two hospitals in CBSA 43524 that have not reported their nursing wages accurately. The cost report data drives the rates for post-acute Medicare services such as hospice; this difference should be taken into consideration.

Response: We would like to thank the commenter for her comment. We disagree with the commenter's statement that hospitals in Maryland have no incentives for ensuring the accuracy of their cost reports and that the cost report data are inaccurate and not representative of the costs that the hospitals actually incur. Hospitals' cost reports, including those of hospitals in Maryland, are required to be certified by the Officer or Administrator of the hospital. The hospital Medicare Cost Report (MCR) Form (CMS–2552–10) states the following:

''I HEREBY CERTIFY that I have read the above statement and that I have examined the accompanying cost report and the Balance Sheet and Statement of Revenue and Expenses prepared by _____ _____((provider name(s) and number(s) for the cost report beginning _____a and ending _____a and to the best of my knowledge and belief, this report and statement are true, correct, complete and prepared from the books and records of the provider in accordance with applicable instructions, except as noted. I further certify that I am familiar with the laws and regulations regarding the provision of health care services, and that the services identified in this cost report were provided in compliance with such laws and regulations.''

We also note that the hospital Medicare cost report referenced statement above includes the following:

''Misrepresentation or falsification of any information contained in this cost report may be punishable by criminal, civil and administrative action, fine and/or imprisonment under federal law. Furthermore, if services identified in this report were provided or procured through the payment directly or indirectly of a kickback or were otherwise illegal, criminal, civil and administrative action, fines and/or imprisonment may result.''

As always, we encourage providers to fill out the Medicare cost reports as accurately as possible.

Comment: A commenter stated that no hospice should receive a wage index below the hospital rural floor. The commenter stated that in some small CBSAs, hospices receive a wage index that is below the rural floor which severely impacts their ability to deliver high-quality hospice care. CMS should mandate that no hospice receive a wage index below the rural floor.

Response: The hospice wage index does not contain a rural floor provision. 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 (for example, SNF PPS, IRF PPS, and HH PPS). The hospice floor is applicable to all CBSAs, both rural and urban. 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.

Comment: A commenter requested that CMS make adjustments to the methodology used to calculate the wage index for rural Puerto Rico. The commenter stated that the proposed ruling for the FY 2018 Hospice Wage Index Update states that ''in cases where there was a rural area without rural hospital wage data, we use the average pre-floor, pre-reclassified hospital wage index data from all contiguous Core-Based Statistical Areas (CBSAs), to represent a reasonable proxy for the

rural area.'' Currently, the only rural area without a hospital from which hospital wage data could be derived is Puerto Rico. The commenter notes that CMS chose not to use this proxy for Puerto Rico and continued using the most recent wage index previously available for that rural area. The commenter does not believe that this represents a ''reasonable proxy for the rural area'' in comparison with other jurisdictions, and it still does not justify applying lower wage indices to urban areas in Puerto Rico.

The commenter proposes that CMS should use the wage index defined for the neighboring U.S. Virgin Islands for CY 2018, as this would be in harmony with the policy defined for Part B GPCIs, by providing more consistency across the payment policies among neighboring Territories. Alternatively, the commenter proposes that Puerto Rico wage indices in Hospice care should not be lower than the average ratio of Puerto Rico wages to U.S. wages, using the data from the OES. The Puerto Rico average wage is at 58 percent of the national average, the commenter considers that the Hospice wage index should be at least equal to that ratio.

Response: We will take these comments under consideration for any future policy changes that may be considered for Puerto Rico. The wage index value for rural Puerto Rico is increased by 15 percent in accordance with the hospice floor provision. There was an error in the Proposed FY 2018 Hospice Wage Index file. The value for rural Puerto Rico was listed as 0.4047. The correct value is 0.4654.

Comment: A commenter expressed dissatisfaction with the wage index value for Madera County, California in relation to the wage index value for Fresno County, which is adjacent to Madera County.

Response: As stated earlier in this final rule, we use OMB's geographic area delineations to differentiate between labor markets. Based on the most recent list of MSA definitions contained in OMB Bulletin No. 15–01, published on July 15, 2015 and available at *https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/bulletins/2015/15-01.pdf*, Madera County is associated with a different MSA than Fresno County. Therefore, for payment purposes we calculate these two counties wage indices separately, based on data gathered from the cost reports of the Inpatient Prospective Payment System (IPPS) hospitals in those counties.

Comment: One commenter expressed concern that the proposed FY 2018 hospice wage index will be fully based on the new OMB geographic area wage delineations. The commenter was particularly concerned with the New York City CBSA and the fact that the CBSA contains counties from New Jersey where labor costs are lower.

Response: We responded to this comment in the FY 2017 Hospice Wage Index and Payment Rate Update final rule (81 FR 52154). We continue to believe that the OMB's geographic area delineations are a reasonable and appropriate method of defining geographic areas for the purposes of wage adjusting the hospice payment rates.

Comment: A commenter was concerned with the continued use of the pre-floor, pre-reclassified hospital wage index to adjust the hospice payment rates and states his belief that this causes continued volatility of the hospice wage index from one year to the next. The commenter believes that the volatility is often based on inaccurate or incomplete hospital cost report data.

Response: We addressed this comment in the FY 2017 Hospice Wage Index and Payment Rate Update final rule (81 FR 52154). We continue to believe that the annual changes in the wage index reflect real variations in costs of providing care in various geographic locations. 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. 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 our policy of utilizing a hospice wage index standardization factor, which was proposed and finalized in FY 2017 rulemaking, provides 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: We responded to this comment in the FY 2017 Hospice Wage Index and Payment Rate Update final rule (81 FR 52154) and believe that it is important to reiterate that the regulations and statutes that govern hospice payments do not provide 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 in section 1886(d) of the Act. In addition, we do not believe that using hospital reclassification data would be appropriate, as these data are specific to the requesting hospitals and they may or may not apply to a given hospice in a given instance. In addition, several post-acute care payment systems utilize the pre-floor, pre-reclassified hospital wage index as the basis for their wage indices (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)).

Final Decision: 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 2018, 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).

The wage index applicable for FY 2018 is available on our Web site at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/Hospice/index.html*. The hospice wage index for FY 2018 will be effective October 1, 2017 through September 30, 2018.

2. FY 2018 Hospice Payment Update Percentage

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 to be updated by a factor equal to the inpatient hospital market basket percentage increase 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 increase for that FY. The Act historically required us to use the inpatient hospital market basket as the basis for the hospice payment rate update.

Section 3401(g) of the Affordable Care Act mandated that, starting with FY 2013 (and in subsequent FYs), the hospice payment update percentage would 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). In addition to the MFP adjustment, section 3401(g) of the Affordable Care Act also mandated that in FY 2013 through FY 2019, the hospice payment update percentage would 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).

Prior to the enactment of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) (Pub. L. 114–10, enacted April 16, 2015), which amended section 1814(i)(1)(C) of the Act, the proposed hospice update percentage for FY 2018 would have been based on the estimated inpatient hospital market basket update of 2.7 percent (based on IHS Global Inc.'s second quarter 2017 forecast with historical data through the first quarter of 2017 of the 2014-based IPPS market basket). Due to the requirements at section 1886(b)(3)(B)(xi)(II) of the Act prior to enactment of the MACRA, the estimated FY 2018 inpatient hospital market basket update of 2.7 percent would have been reduced by a MFP adjustment as mandated by Affordable Care Act (currently estimated to be 0.6 percentage point for FY 2018) and a 0.3 percentage point reduction as mandated by section 1814(i)(1)(C)(v) of the Act. In effect, the hospice payment update percentage for FY 2018 would be 1.8 percent. However, section 411(d) of the MACRA amended section 1814(i)(1)(C) of the Act, such that for hospice payments for FY 2018, the market basket percentage increase is required to be 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. Beginning with cost reporting periods starting on or after October 1, 2014, freestanding hospice providers are required to submit cost data using CMS Form 1984–14 (*https://www.cms.gov/Research-Statistics-Data-and-Systems/Downloadable-Public-Use-Files/Cost-Reports/Hospice-2014.html*). We are currently analyzing this data for possible use in updating the labor portion of the hospice payment rates. Any changes to the labor portions will be proposed in future rulemaking and will be subject to public comments.

A summary of the comments we received regarding the payment update and our responses to those comments appear below.

Comment: Several commenters stated that the FY 2018 payment update of 1 percent is inadequate. One of the commenters stated that the update does not appropriately keep pace with the cost of providing hospice care to beneficiaries and does not match the increasing costs associated with data collection requirements and reporting, technology, workforce and training.

Response: We appreciate the commenter's concerns; however, the 1 percent payment update for FY 2018 is mandated by section 411(d) of the MACRA.

Comment: A commenter noted that in MedPAC's March 2017 Report to Congress, MedPAC concluded that indicators of payment adequacy for hospice providers are generally positive. In 2015, the number of hospices increased about 2.6 percent because of continued entry of for-profit providers. The aggregate Medicare margin was 8.2 percent in 2014 and MedPAC projected a 2017 aggregate Medicare margin of 7.7 percent. Based on their assessment of these and other payment adequacy indicators, MedPAC concluded that hospices should be able to accommodate cost changes in 2018 without an update to the 2017 base payment rate. The commenter also acknowledged that CMS is required by statute to update the FY 2018 hospice payment rates by 1 percent.

Response: We thank the commenter for noting that hospices' Medicare margins appear to be adequate and no update to the per diem amounts is needed for FY 2018. We further thank the commenter for acknowledging that we do not have the authority to eliminate the payment update for FY 2018.

3. FY 2018 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 CHC, IRC, or GIP. CHC is provided during a period of patient crisis to maintain the patient at home; IRC is short-term care to allow the usual caregiver to rest and be relieved from caregiving; and 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 for RHC for 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, if certain criteria are met. 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 2018, we calculated the SBNF using FY 2016 utilization data. We examined skilled nursing and social work visit data for the last 7 days of life where RHC was billed and found that, from January 1

through September 30, 2016, approximately 86 percent of nursing visits were identified as RN visits (using G0299) and 14 percent of nursing visits were identified as Licensed Practical Nurse (LPN) visits (using G0300). Because the differentiated nursing visit G-codes were not implemented until January 1, 2016, for skilled nursing visits during the last 7 days of life where RHC was billed and that occurred between October 1 and December 31, 2015, we estimated that 86 percent of the line item visits reported using G0154 were RN and 14 percent were LPN using statistics generated for the 2016 time period where data were available. For FY 2018, the budget neutrality adjustment that would apply to days 1 through 60 is calculated to be 1.0017. The budget neutrality adjustment that would apply to days 61 and beyond is calculated to be 1.0005.

In the FY 2017 Hospice Wage Index and Payment Rate Update final rule (81 FR 52156), we initiated a policy of applying a wage index standardization factor to hospice payments in order to eliminate the aggregate effect of annual variations in hospital wage data. In order to calculate the wage index standardization factor, we simulate total payments using the FY 2018 hospice wage index and compare it to our simulation of total payments using the FY 2017 hospice wage index. By dividing payments for each level of care using the FY 2018 wage index by payments for each level of care using the FY 2017 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). The wage index standardization factors for each level of care are shown in the tables below.

Lastly, the hospice payment rates for hospices that submit the required quality data would be increased by the FY 2018 hospice payment update percentage of 1.0 percent as discussed in section III.B.2 of this final rule. The FY 2018 RHC rates are shown in Table 12. The FY 2018 payment rates for CHC, IRC, and GIP are shown in Table 13.

TABLE 12—FY 2018 HOSPICE RHC PAYMENT RATES

Code	Description	FY 2017 payment rates	SIA budget neutrality factor	Wage index standardization factor	FY 2018 hospice payment update	FY 2018 payment rates
651	Routine Home Care (days 1–60)	$190.55	× 1.0017	× 1.0000	× 1.01	$192.78
651	Routine Home Care (days 61+)	149.82	× 1.0005	× 1.0001	× 1.01	151.41

TABLE 13—FY 2018 HOSPICE CHC, IRC, AND GIP PAYMENT RATES

Code	Description	FY 2017 payment rates	Wage index standardization factor	FY 2018 hospice payment update	FY 2018 payment rates
652	Continuous Home Care; Full Rate = 24 hours of care; $40.68 = FY 2018 hourly rate.	$964.63	× 1.0022	× 1.01	$976.42
655	Inpatient Respite Care	170.97	× 1.0006	× 1.01	172.78
656	General Inpatient Care	734.94	× 1.0017	× 1.01	743.55

Sections 1814(i)(5)(A) through (C) of the Act require that hospices submit 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 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 2018 rates for hospices that do not submit the required quality data would be updated by the FY 2018 hospice payment update percentage of 1 percent minus 2 percentage points. These rates are shown in Tables 14 and 15.

TABLE 14—FY 2018 HOSPICE RHC PAYMENT RATES FOR HOSPICES THAT DO NOT SUBMIT THE REQUIRED QUALITY DATA

Code	Description	FY 2017 payment rates	SIA budget neutrality factor	Wage index standardization factor	FY 2018 hospice payment update of 1% minus 2 percentage points = −1.0%	FY 2018 payment rates
651	Routine Home Care (days 1–60)	$190.55	× 1.0017	× 1.0000	× 0.99	$188.97
651	Routine Home Care (days 61+)	149.82	× 1.0005	× 1.0001	× 0.99	148.41

TABLE 15—FY 2018 HOSPICE CHC, IRC, AND GIP PAYMENT RATES FOR HOSPICES THAT *DO NOT* SUBMIT THE REQUIRED QUALITY DATA

Code	Description	FY 2017 payment rates	Wage index standardization factor	FY 2018 hospice payment update of 1% minus 2 percentage points = −1.0%	FY 2018 payment rates
652	Continuous Home Care; Full Rate = 24 hours of care; $39.88 = FY 2018 hourly rate.	$964.63	× 1.0022	× 0.99	$957.08
655	Inpatient Respite Care	170.97	× 1.0006	× 0.99	169.36
656	General Inpatient Care	734.94	× 1.0017	× 0.99	728.83

4. Hospice Cap Amount for FY 2018

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). The hospice cap amount for the 2018 cap year will be $28,689.04, which is equal to the 2017 cap amount ($28,404.99) updated by the FY 2018 hospice payment update percentage of 1.0 percent.

A summary of the comments we received regarding the hospice cap amount and our responses to those comments appears below.

Comment: One commenter noted that the hospice cap is a uniform amount meaning that each CBSA has the same cap amount. The commenter ascertains that in certain CBSAs, the hospice per diem rate is significantly higher than the national average. The commenter believes that since the cap amount does not adjust relative to CBSA, Medicare beneficiaries in CBSAs with higher wage indices have significantly fewer potential days of hospice care available to them relative to beneficiaries who reside in CBSAs with a lower wage indices. Accordingly, the commenter recommends that, in fairness to providers located in CBSAs with higher than average wage indices, CMS adjust the hospice cap amount by CBSA.

Response: We appreciate the commenter's suggestion that CMS wage-adjust the annual cap amount. However, the restriction set forth in section 1814(i)(2)(B), as amended by section 3(d) of the IMPACT Act, does not give us discretion to adjust the cap amount.

C. Discussion Regarding Sources of Clinical Information for Certifying Terminal Illness

In accordance with the regulations at § 418.20, a patient must be certified as terminally ill in order to be eligible to elect the Medicare Hospice benefit. Furthermore, hospice admission is predicated on the certification of terminal illness that determines eligibility. In reaching a decision to certify, § 418.25 requires a hospice medical director to consider the diagnosis of the terminal condition of the patient, other health conditions (whether related or unrelated to the terminal condition), and current clinically relevant information supporting all diagnoses. In the FY 2018 Hospice Wage Index and Payment Rate Update proposed rule, we discussed a potential proposal for a regulatory text change at § 418.25, clarifying that the documentation used for the initial certification must come from the referring physician's or acute/post-acute care facility's medical records (84 FR 20771). We also discussed the potential benefit of an initial face-to-face visit by the hospice medical director or physician designee, if needed, to support the clinical documentation required to accompany the certification of terminal illness. Although we did not propose this regulatory change, we requested public input on the possible amendment. We solicited comments on current processes used by hospices to ensure comprehensive clinical review to support certification, and encouraged submission of any alternate suggestions for supporting clinical documentation sources that ensure appropriate hospice admission.

Comment: A few commenters expressed support for the potential regulations text change, and stated that they consider ''obtaining and analyzing medical records from the referring provider'' to be ''best practice.'' Additionally, commenters indicated that their processes for certification already include review of the referring source's clinical documentation, which one commenter noted includes review of ''pathology reports, blood work reports, x-rays, kidney function, heart function, PPS assessment, mental assessment, medications, goals of care, diagnosis, nutritional assessment, weight loss, BMI and any other hospital report available that would indicate the patient has 6 months or less to live.'' A few commenters specifically noted that the regulations at § 418.22(b) specify that clinical information and other documentation that supports the patient's prognosis must accompany the certification and that hospices receive clinical information from a variety of sources; therefore, a change in the regulations at § 418.25 is not needed.

Response: We thank commenters for their support. We understand from commenters that hospices already obtain and analyze clinical information from a variety of sources, including referring providers, and we agree that the regulations at § 418.22(b) require such information to accompany the certification of terminal illness. While we are not proposing a change in the regulations at this time, we plan to work with our Medicare Administrative Contractors (MACs) to confirm whether they are requesting such information when claims are selected for medical review and, if not, whether such information should be included in any additional documentation requests. We continue to encourage providers to use the full range of clinical documentation when certifying terminal illness in order to ensure physician engagement and accountability.

Comment: The majority of commenters expressed concerns that obtaining clinical documentation from outside physicians or facilities would delay hospice admission and services. In addition, commenters expressed concern that CMS was considering requiring hospice physicians to perform a face-to-face visit within the 2 day

certification time frame in order to certify terminal illness.

Response: The discussion in the FY 2018 Hospice Wage Index and Payment Rate Update proposed rule was meant only to solicit comments on clarifying the source of the clinical information already required to be reviewed by the hospice medical director upon the initial certification. Therefore, this clinical information can be obtained orally from the referring entity and documented in the patient's chart within the 2 day time-frame needed for certification. We stated in the November 22, 2005 Hospice Care Amendments final rule that the clinical information may initially arrive verbally and is documented in the patient's medical record as part of the hospice's assessment of eligibility for hospice. The referring entity's clinical documentation may arrive later for retention in the patient's medical record (70 FR 70539). We believe that clinical information and documentation are critical to the certification decision and this information is needed for the hospice's interdisciplinary group (IDG) to develop the initial plan of care for the new patient and, therefore we would expect the information to accompany, in some fashion, the certification. Likewise, the requirement that the medical documentation that accompanies the initial written certification be obtained prior to submitting a claim remains unchanged and should not impede services. The hospice admission assessment can also accompany the initial written certification; however, this information should further substantiate rather than provide the basis for certification.

We would also like to clarify that the hospice medical director or physician designee would not be required to perform a face-to-face visit before the third benefit period recertification, as currently required by the regulations at § 418.22(a)(4). Rather, the intent of the discussion and solicitation of comments in the FY 2018 Hospice Wage Index and Payment Rate Update proposed rule was to determine whether such optional visits could be useful to augment the referral source's clinical documentation to support a medical prognosis of 6 months or less.

We appreciate and thank all commenters for providing feedback on this discussion. We will carefully consider all comments for any future rulemaking proposals, if needed, regarding the sources of clinical information to support the certification of terminal illness.

D. 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 year 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 a 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 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/reports/annual-reports/nqs2015annlrpt.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) (*http://www.nationalconsensusproject.org/Default.aspx*), recommended by multi-stakeholder organizations, and developed with the input of providers, purchasers/payers, and other stakeholders.

In the FY 2018 Hospice proposed rule (82 FR 20773 through 20774), we discussed accounting for social risk factors in the HQRP. We stated that we consider related factors that may affect measures in the HQRP. We understand that social risk factors such as income, education, race and ethnicity, employment, disability, community resources, and social support (certain factors of which are also sometimes referred to as socioeconomic status (SES) factors or socio-demographic status (SDS) factors) play a major role in health. One of our core objectives is to improve beneficiary outcomes including reducing health disparities, and we want to ensure that all beneficiaries, including those with social risk factors, receive high quality care. In addition, we seek to ensure that the quality of care furnished by providers and suppliers is assessed as fairly as possible under our programs while ensuring that beneficiaries have adequate access to excellent care.

We have been reviewing reports prepared by the Office of the Assistant Secretary for Planning and Evaluation (ASPE) [4] and the National Academies of Sciences, Engineering, and Medicine on the issue of measuring and accounting for social risk factors in CMS' quality measurement and payment programs, and considering options on how to address the issue in these programs. On December 21, 2016, ASPE submitted a Report to Congress on a study they were required to conduct under section 2(d) of the Improving Medicare Post-Acute Care Transformation (IMPACT) Act of 2014. The study analyzed the effects of certain social risk factors of Medicare beneficiaries on quality measures and measures of resource use used in one or more of nine Medicare value-based purchasing programs.[5] The report also included considerations for strategies to account for social risk factors in these programs. In a January 10, 2017, report released by The National Academies of Sciences, Engineering, and Medicine, that body provided various potential methods for measuring and accounting for social risk factors, including stratified public reporting.[6] In addition, the NQF undertook a 2-year trial period in which new measures, measures undergoing maintenance review, and measures endorsed with the condition that they enter the trial period were assessed to determine whether risk adjustment for selected social risk factors was appropriate for these measures. This trial entailed temporarily allowing inclusion of social risk factors in the risk-adjustment approach for these measures. The trial has concluded and NQF will issue recommendations on the future inclusion of social risk factors in risk adjustment for quality measures.

As we continue to consider the analyses and recommendations from these reports and await the recommendations of the NQF trial on risk adjustment for quality measures, we are continuing to work with stakeholders in this process. As we have previously communicated, we are concerned about holding providers to different standards for the outcomes of their patients with social risk factors because we do not want to mask potential disparities or minimize incentives to improve the outcomes for disadvantaged populations. Keeping this concern in mind, while we sought input on this topic previously, we continue to seek public comment on whether we should account for social risk factors in measures in the HQRP, and if so, what method or combination of methods would be most appropriate for accounting for social risk factors. Examples of methods include: Confidential reporting to providers of measure rates stratified by social risk factors, public reporting of stratified measure rates, and potential risk adjustment of a particular measure as appropriate based on data and evidence.

In addition, in the proposed rule, we sought public comment on which social risk factors might be most appropriate for reporting stratified measure scores and/or potential risk adjustment of a particular measure. Examples of social risk factors include, but are not limited to, dual eligibility/low-income subsidy, race and ethnicity, and geographic area of residence. We also sought comments on which of these factors, including current data sources where this information would be available, could be used alone or in combination, and whether other data should be collected to better capture the effects of social risk. We will take commenters' input into consideration as we continue to assess the appropriateness and feasibility of accounting for social risk factors in the HQRP. We note that any such changes would be proposed through future notice and comment rulemaking.

We look forward to working with stakeholders as we consider the issue of accounting for social risk factors and reducing health disparities in CMS programs. Of note, implementing any of the above methods would be taken into consideration in the context of how this and other CMS programs operate (for example, data submission methods, availability of data, statistical considerations relating to reliability of data calculations, among others), so we sought comment on operational considerations. We are committed to ensuring that its beneficiaries have access to and receive excellent care, and that the quality of care furnished by providers and suppliers is assessed fairly in our programs.

We received many comments in response to our request for public comment on whether we should account for social risk factors in the Hospice Quality Reporting Program.

Comment: Commenters were supportive of CMS accounting for social risk factors however, the majority of the commenters cautioned that social risk factors should be used to inform only outcome quality measures. Specifically, they were not supportive of identifying social risk factors for process measures or direct impacts of care under the hospice's control. Several commenters were concerned about quality measures for items that a hospice has minimal control over and many of these items are under discussion for risk adjustment.

Regarding methodology for adjustment, overall, commenters were supportive of risk adjustment in general, but a few commenters indicated preference for stratification or peer grouping, due to the minimal measure-level research required and low impact on provider incentives to improve care when their adjusted performance is transparent. One commenter suggested using standard statistical methodology and adopting the approach used for adjusting CAHPS® data. Prior to conducting social risk factor stratification, however, a few commenters noted that they would like for CMS to evaluate and disseminate the testing results from the NQF and solicit provider comment on the results. Several commenters encouraged CMS to determine the feasibility and appropriateness of identifying social risk factors, and a couple commenters recommended involving hospice providers in determining appropriate social risk factors and associated outcome measures. One commenter recommended piloting the outcome measures with social risk factors in advanced care planning pilot instead of incorporating them with current hospice measures. However, several commenters expressed concern that risk adjusting may lead to the unintended consequences of discouraging providers from admitting patients with identified social risk factors, and enabling providers to deliver sub-optimal care to disadvantaged populations. One commenter noted providers wishing to maintain or improve scores on quality measures may consider exclusively admitting patients who will demonstrate positive care outcomes. Another commenter emphasized that patients impacted by many social risk factors require intensified, complex care at end of life, so CMS should not unfairly penalize providers when taking these patient needs and challenges into account in the quality measurement process. Additionally, commenters offered specific suggestions for types of social risk factors to identify and recommended ways CMS could manage the testing, data collection, and reporting. In commenters' discussion of suggested social risk factors, a few

[4] *https://aspe.hhs.gov/pdf-report/report-congress-social-risk-factors-and-performance-under-medicares-value-based-purchasing-programs.*

[5] *https://aspe.hhs.gov/pdf-report/report-congress-social-risk-factors-and-performance-under-medicares-value-based-purchasing-programs.*

[6] National Academies of Sciences, Engineering, and Medicine. 2017. Accounting for social risk factors in Medicare payment. Washington, DC: The National Academies Press.

commenters drew attention to how adjustment should be conducted on a measure-specific basis, as different social risk factors affect different outcomes such as caregiver satisfaction and care delivery. In addition to support for CMS's suggested categories of race and ethnicity, dual eligibility status, and geographical location, many commenters emphasized adjusting for family dynamics, such as the patient's relationship with the family, accessibility/availability of an adequate caregiver, history of substance abuse in the family, and psychosocial acuity. Other commenters promoted education level, literacy and health literacy levels, mental health, rurality and English as a second language. A few commenters highlighted adjusting for Medicaid-covered services in the area and income-subsidy levels. Some emphasized that core-based statistical area (CBSAs), geographical location of patient residence, and driving distance to home locations are important because they impact timeliness of care delivery. One commenter noted adequate and safe housing impacts the hospice's ability to deliver care. A few commenters suggested adjusting for length of stay, as patient needs will require differing acuities of care for short and long stays. One commenter requested that extraction of social risk factors pose low burden for providers. A few commenters discussed public display of data adjusted for social risk factors. One commenter suggested displaying both unadjusted and adjusted data in confidential feedback reports as a means of provider performance improvement before publicly reporting adjusted data to be used for determining reimbursement.

Response: As we have previously stated, we are concerned about holding providers to different standards for the outcomes of their patients with social risk factors, because we do not want to mask potential disparities. We believe that the path forward should incentivize improvements in health outcomes for disadvantaged populations while ensuring that beneficiaries have adequate access to excellent care. We will consider all suggestions as we continue to assess each measure and the overall program. We intend to explore options including but not limited to measure stratification by social risk factors in a consistent manner across programs, informed by considerations of stratification methods described in the upcoming FY 2018 Inpatient Prospective Payment System/Long-Term Care Hospital Prospective Payment System (IPPS/LTCH PPS) final rule, which is expected to publish in the **Federal Register** shortly after this final rule. We thank commenters for this important feedback and will continue to consider options to account for social risk factors that would allow us to view disparities and potentially incentivize improvement in care for patients and beneficiaries. We will also consider providing feedback to providers on outcomes for individuals with social risk factors in confidential reports.

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 us for reasons including, but not limited to the following:

- 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 unavailable.
- A measure that was more proximal in time to desired patient outcomes for the particular topic was not available.
- A measure that was more strongly associated with desired patient outcomes for the particular topic was not available.
- 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 was reason to believe continued inclusion of a measure in the HQRP would encourage delivery of care that 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 CMS HQRP Web site, listserv messages via the Post-Acute Care Quality Reporting Program listserv,[7] Medicare Learning Network (MLN) Connects® National Provider Calls & Events, MLN Connects® Provider eNews. Following immediate removal of the measures, we would also notify the public of any such removal in the next annual rulemaking cycle. CMS expects immediate removal of a measure due to safety concerns to be an unlikely event, given the rigorous testing and analysis all measures undergo prior to adoption in the HQRP.

4. Policy for Adopting Changes to Previously Adopted Measures

To further streamline the rulemaking process, we finalized in the FY 2017 Hospice Wage Index final rule (81 FR 52159) that if measures in the HQRP undergo non-substantive changes in specifications as part of their NQF re-endorsement process, we would subsequently utilize the measure with their new endorsed status in the HQRP without going through new notice-and-comment rulemaking. 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 or the measure steward's measure maintenance process, measures are sometimes updated to incorporate changes that we believe do not substantively change the intent of the measure. Examples of such changes may include updated diagnosis or procedure codes or changes to

[7] CMS, Post-Acute Care QRP listerv, available at: *https://public-dc2.govdelivery.com/accounts/USCMS/subscriber/new?topic_id=USCMS_12265.*

exclusions to the patient population or definitions. While we address such changes on a case-by case basis, we generally believe these types of maintenance changes are distinct from substantive changes to measures that result in what are considered new or different 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,[8] we believe that the NQF measure endorsement and maintenance process itself is transparent, scientifically rigorous, and provides opportunity for public input. Thus, we finalized our proposal 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 (81 FR 52159 through 52160). If NQF-endorsed specifications change and we do not adopt those changes, then we would propose the measure as a modification. A modification of a NQF-endorsed quality measure is utilized in instances when we have 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, ''[i]n 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 the prior 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 CMS HQRP Web site, listserv messages on the Post-Acute Care QRP listserv, MLN Connects® National Provider Calls & Events, MLN Connects® Provider eNews and announcements on Open Door Forums and Special Open Door Forums.

5. Previously Adopted Quality Measures for FY 2018 Payment Determination and Future Years

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 7 NQF-endorsed measures 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).[6]

We finalized the following two additional measures in the FY 2017 Hospice Wage Index final rule effective April 1, 2017. Data collected will, if not reported, affect payments for FY 2019 and subsequent years. (81 FR 52163 through 52173):

- Hospice Visits when Death is Imminent
- Hospice and Palliative Care Composite Process Measure—Comprehensive Assessment at Admission

We finalized the HIS effective July 1, 2014 (78 FR 48258). The HIS is the data collection mechanism for all of the aforementioned measures. 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). For the two measures finalized in the FY 2017 Hospice Wage Index final rule, we require regular and ongoing electronic submission for each patient admission to hospice after April 1, 2017. 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. Table 16 provides a summary of measures previously finalized affecting the FY 2019 APU, data collection mechanism, and data submission deadline.

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 2017 will have their market basket update reduced by 2 percentage points in FY 2019 (beginning in October 1, 2018). 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 entitled ''Hospice Item Set (HIS) System,'' SOR number 09–70–0548, was published in the **Federal Register** on April 8, 2014 (79 FR 19341).

The 7 NQF endorsed HIS measures adopted in FY 2014 Hospice Wage Index final rule successfully underwent NQF Endorsement Maintenance in 2016.[9] We recognize that the NQF endorsement process is an important part of measure development and plan to submit the two measures finalized in the FY 2017 Hospice Wage Index final rule for NQF endorsement once sufficient measure data are available and we conduct the analyses necessary to support NQF submission for endorsement (for example, reliability and validity analyses). Typically, we need at least 4 quarters worth of data to conduct the necessary analyses and establish measure reliability and validity. Because the Hospice and Palliative Care Composite Process Measure—Comprehensive Assessment at Admission did not require any new data collection and can be calculated using existing data, CMS's measure development contractor, RTI

[8] ''NQF: How Endorsement Happens—National Quality Forum.'' 2010. 26 Jan. 2016 *http://www.qualityforum.org/Measuring_Performance/ABCs/How_Endorsement_Happens.aspx.*

[9] National Quality Forum, *NQF Palliative and End-of-Life Care 2015–2016 Report,* available at: *http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=84242.*

International, has already conducted the analyses necessary to support submission of the measure for NQF endorsement. We have already submitted the Hospice and Palliative Care Composite Process Measure for consideration for endorsement at NQF (NQF #3235); the measure is currently under review. Data for the Hospice Visits when Death is Imminent measure pair will be collected using new items added to the HIS V2.00.0, effective April 1, 2017. Once data collection for the measure pair begins, we will need at least 4 quarters of reliable data to conduct the necessary analyses to support submission to NQF. We will also need to assess the quality of data submitted in the first quarter of item implementation to determine whether they can be used in the analyses. Pending analysis, we will submit the Hospice Visits when Death is Imminent measure pair to NQF for endorsement review in accordance with NQF project timelines and call for measures. In the FY 2015 Hospice Wage Index final rule (79 FR 50491 through 50496), we also finalized the Consumer Assessment of Healthcare Providers and Systems (CAHPS®) Hospice Survey to support quality measures based on patient and family experience of care. We refer readers to section III.D.11 of the May 3, 2017 proposed rule (82 FR 20750 through 20792) for details regarding the CAHPS® Hospice Survey, including public reporting of selected survey measures.

TABLE 16—PREVIOUSLY FINALIZED QUALITY MEASURES AFFECTING THE FY 2019 PAYMENT DETERMINATION AND SUBSEQUENT YEARS

NQF No.	Hospice item set quality measure	Year the measure was first adopted for use in APU determination
1641	Treatment Preferences	FY 2016
1647	Beliefs/Values Addressed (if desired by the patient)	FY 2016
1634	Pain Screening	FY 2016
1637	Pain Assessment	FY 2016
1639	Dyspnea Screening	FY 2016
1638	Dyspnea Treatment	FY 2016
1617	Patients Treated with an Opioid Who Are Given a Bowel Regimen	FY 2016
N/A	Hospice and Palliative Care Composite Process Measure—Comprehensive Assessment at Admission	FY 2019
N/A	Hospice Visits When Death is Imminent Measure Pair	FY 2019

The comment and our response are set forth below.

Comment: We received several comments on previously adopted quality measures, including measure refinement suggestions for the Hospice Visits when Death is Imminent Measure Pair. One commenter suggested that CMS include a way to capture whether visits were offered but declined. Another commenter noted that frequent visits by hospice staff may not be necessary or desired by all patients and encouraged CMS to include evidence of a need or desire for these visits in the measure specifications. We received one comment recommending risk adjustment for the Visits Measure Pair.

Response: The Visits when Death is Imminent Measure Pair is a measure that was previously proposed and finalized in the HQRP. We refer readers to the FY 2017 Hospice Wage Index final rule (81 FR 52162 through 52169) for a detailed discussion of measure specifications for this measure pair, including discussion of why refused visits were not included in measure specifications, as well as discussion on risk adjustment. We invite the public to submit questions or suggestions about previously finalized and currently implemented proposals through sub-regulatory communication channels, including the Hospice Quality Help Desk at *HospiceQualityQuestions@cms.hhs.gov*, and through other communication channels such as Open Door Forums and Special Open Door Forums.

6. Removal of Previously Adopted Measures

We did not propose to remove any of the current HQRP measures at this time. Any future proposals regarding removal, suspension, or replacement of measures will be proposed here in this preamble of future rules. As stated in section III.D.3 of the FY 2018 Hospice Wage Index proposed rule (82 FR 20750), a quality measure that is adopted and implemented in the HQRP will be retained for all subsequent years, unless the measure is proposed for removal, suspension, or replacement by CMS. Policies and criteria for removing a measure were also discussed.

7. Measure Concepts Under Consideration for Future Years

Although we did not propose any HIS-based measures, we have measure concepts under consideration for future years. Our paramount concern is to develop quality measures that promote care that is person-centered, high quality, and safe. We continue to work with our measure development contractor, RTI International, to identify measure concepts for future implementation in the HQRP. In identifying priority areas for future measure enhancement and development, we take into consideration input from numerous stakeholders, including the MAP, the MedPAC, Technical Expert Panels (TEP), and national priorities, such as those established by the Department of Health and Human Services (HHS) Strategic Plan, the National Strategy for Quality Improvement in Healthcare, and the CMS Quality Strategy. In addition, we take into consideration vital feedback and input from research published by our payment reform contractor. 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, including current HIS measures and CAHPS® Hospice Survey measures, without creating unnecessary burden or redundant reporting. Based on input from stakeholders, we identified two high priority areas that will be addressed by claims-based measure development. Developing quality measures using claims does not require new data collection, thus minimizing provider burden and expediting implementation.

Priority Area 1: Potentially Avoidable Hospice Care Transitions

The concept of a claims-based measure focusing on transitions of care was first introduced in the FY 2016 Hospice Wage Index final rule (80 FR 47188 through 47189). Comments received during this rule were overall supportive of our efforts to develop more robust quality measures that capture hospice performance and show links to patient and family outcomes. We refer readers to the FY 2016 Hospice Wage Index final rule (80 FR 47188 through 47189) and for additional details: *https://www.gpo.gov/fdsys/pkg/FR-2015-08-06/pdf/2015-19033.pdf.*

Potentially avoidable hospice care transitions at end of life are burdensome to patients, families, and the health care system at large, because they are associated with adverse health outcomes, lower patient and family satisfaction, higher health care costs, and fragmentation of care delivery.[10] [11] [12] [13] [14] By encouraging hospice providers to assess and manage patients' risk of care transitions, this measure concept has the potential to improve quality care at the end of life by reducing potentially avoidable hospice care transitions.

Priority Area 2: Access to Levels of Hospice Care

The Medicare Hospice Benefit covers four levels of care to meet patients' and families' clinical needs: Routine home care (RHC), continuous home care (CHC), general inpatient care (GIP), and inpatient respite care. The goal of this measure concept is to assess the rates at which hospices provide different levels of hospice care. The measure has the potential to improve access to various levels of care for patients and caregivers. Appropriate use of CHC and GIP increases the likelihood of a hospice patient dying in his or her location of choice, decreases health resource utilization resulting in potential cost savings, and increases patient and caregiver satisfaction.[15] [16] Measuring use of levels of care will encourage hospice providers to continuously assess patient and caregiver needs and provide the appropriate level of care to meet these needs. These two measure concepts are under development, and details regarding measure definitions, specifications and timeline for implementation will be communicated in future rulemaking.

We solicited comments regarding high priority measure areas for future measure development including two specific measures under consideration related to: (1) Potentially avoidable hospice care transitions, and (2) access to levels of hospice care.

The comments and our responses have been grouped below: (1) Comments applying to both high priority measure areas, (2) comments specific to the potentially avoidable hospice care transitions measure area, (3) comments specific to the access to levels of hospice care measure area, and (4) other comments and suggestions regarding future HQRP measure development.

Comment: Many commenters agreed that these measure areas were important.

Response: We appreciate the commenters' support of these measure areas as high priority areas for future HQRP measure development.

Comment: Many commenters expressed concerns with the limitations of using claims data for quality measure development. Specifically, commenters were concerned with the limited range of data elements available in claims data. Many commenters stated that claims data do not capture sufficient information about the clinical condition of patients, the preferences and needs of patients and families, or various other factors that influence care planning and decision-making. Several commenters believed that claims do not provide sufficient information to adequately reflect hospice practice. In general, commenters were concerned that, in the absence of these data elements, providers would be unfairly penalized should these measures be implemented.

Response: We recognize that administrative data are not collected for the purpose of quality measure development and thus, claims data lack certain data elements that might be important to consider in constructing quality measures. For example, we agree that patient and family preferences and clinical needs are important factors in determining whether a specific care transition or use of certain level of hospice are appropriate in a specific scenario. We acknowledge the limitations of claims data in capturing this information. However, we would like to clarify that quality measures are not intended to determine whether each individual experience of a care transition or use of a certain level of hospice care, is clinically appropriate. Instead, the measures will present provider-level rates of the process and outcome in the two proposed measure areas, comparing providers to their peers with relevant and available patient-level and hospice-level factors taken into account. Despite the inability to control for certain relevant factors such as patient and family preferences, these factors tend to distribute evenly across hospices. In other words, each hospice may serve patients and families with varying levels of preference for care. As such, the inability to control for these factors does not necessarily disadvantage certain hospices. Regardless, given the limitations of claims data noted above, we are placing careful emphasis on how we construct the specifications of the measure and are using claims data to examine the patient factors that are available and related to the hospice's performance in these measure areas. In addition, we believe that the advantages of using claims data, including minimized burden to providers and expedited implementation, outweigh the limitations of this data source. We will continue to consider the limitations of claims data as we develop specifications for these measure areas. We continue to engage stakeholders in developing measures that provide meaningful information about hospice quality. We will also continue to engage stakeholders and conduct analyses to inform the specifications of these measures.

Comment: Several commenters expressed concerns with the public's ability to understand these measure areas and easily discern their connection to quality. Commenters recommended CMS to ensure that claims-based measures are understandable to the public prior to public reporting.

Response: We appreciate the commenters' concerns regarding public reporting of measures that use claims as a data source. We agree that it is critical

[10] Aldridge MDP, MBA; Epstein, Andrew J. Ph.D.; Brody, Abraham A. RN, Ph.D.; Lee, Eric J. MPH; Cherlin, Emily Ph.D., MSW; Bradley, Elizabeth H. Ph.D. The Impact of Reported Hospice Preferred Practices on Hospital Utilization at the End of Life Medical Care. 2016;54(7):657–663.

[11] Wang S-Y, Aldridge MD, Gross CP, et al. Transitions Between Healthcare Settings of Hospice Enrollees at the End of Life. Journal of the American Geriatrics Society. 2016;64(2):314–322.

[12] Carlson MDA, Herrin J, Du Q, et al. Impact of Hospice Disenrollment on Health Care Use and Medicare Expenditures for Patients With Cancer. Journal of Clinical Oncology. 2010;28(28):4371–4375.

[13] Teno JM, Bowman J, Plotzke M, et al. Characteristics of Hospice Programs With Problematic Live Discharges. Journal of Pain and Symptom Management. 2015;50(4):548–552.

[14] Prsic E, Plotzke M, Christian TJ, Gozalo P, Teno JM. A National Study of Live Hospice Discharges between 2000 and 2012. Journal of Palliative Medicine. 2016;19(9):987–990.

[15] Barclay, J., et al., Association of hospice patients' income and care level with place of death. JAMA Internal Medicine, 2013. 173(6): p. 450–456.

[16] Casarett, D., et al., Does Continuous Hospice Care Help Patients Remain at Home? Journal of Pain and Symptom Management, 2015. 50(3): p. 297–304.

to ensure that quality measures are understandable to the public, especially prior to public reporting of measures. As such, all measures developed and implemented in the HQRP, including claims-based measures, undergo rigorous user testing to ensure that they are understandable to providers and patients and families. For both high priority measure areas, we continue to engage stakeholders including a technical expert panel, caregiver workgroup and clinical users in measure development to ensure that these measures are both meaningful and understandable to the public. In addition, prior to public reporting of these measures, we will provide resources through the Hospice Compare Web site to aid the public in interpreting publicly displayed quality data.

Comment: We received several comments focused on the burden associated with future implementation of the two high priority measure areas. Although most of these commenters applauded CMS for developing measures based on claims data because of the minimal burden for providers associated with their data collection and submission and measure calculation and reporting, one commenter encouraged CMS to carefully consider the burden associated with other aspects of implementing these measure concept areas.

Response: We appreciate the comments regarding the burden associated with the two high priority measure areas. It is our goal to minimize burden for providers when considering any new measure for implementation in the HQRP. Claims-based measures require no additional data collection and submission and thus, minimize burden for providers. We recognize that the implementation of these measures may compel some providers to establish internal systems for monitoring care patterns captured by these measure concepts and are aware that some providers are already doing so. We will consider these internal monitoring and performance improvement efforts within the scope of Quality Assessment and Performance Improvement (QAPI) requirements and other current hospice conditions of participation. We believe such systems may facilitate the appropriate provision of care and prevent unnecessary transitions, thus improving quality of care provided by the hospice. However, we would like to remind providers that no new measures are being proposed in this year's rule, so there will be no additional burden placed on providers.

Comment: Several commenters noted that only a small proportion of hospice patients are discharged alive from hospice. Similarly, they noted that only 2 to 3 percent of billed days in hospice are for levels of care other than Routine Home Care.

Response: We recognize that the two high priority measure areas will capture lower-frequency events. However, studies have demonstrated considerable variation across hospice providers in both measures areas, indicating that some hospices are having a substantially higher rate of live discharges [17] or provide very little or no GIP or CHC care to their patients compared to other providers.[18] [19] This signals performance gaps and, by developing and implementing these measures, we hope to capture these important quality issues. Additionally, low-frequency events can still reveal important quality issues and gaps in care that hospices should address and consumers should be aware of. Thus, measurement of low-frequency events is still important. Hospice patients are likely to need these services as their care needs change, especially as they approach the end of life, so monitoring access to these services will help encourage providers to continually assess patient need.

Moreover, both measure concepts show relationship with patient and family outcomes. Care transitions from hospice including live discharge can result in adverse health outcomes, lower patient and family satisfaction, higher health care costs, and fragmentation of care delivery.[20] [21] [22] [23] [24] In regards to the access to levels of hospice care measure, though only about 2 percent of days are billed as higher intensity levels of care (for example, CHC and GIP), a higher proportion of patients use at least one of these higher intensity levels of care at some point during their stay. Appropriate use of CHC and GIP increases the likelihood of a hospice patient dying in his or her location of choice, decreases health resource utilization resulting in potential cost savings, and increases patient and caregiver satisfaction.[25] [26] [27] Given the potentially severe consequences of receiving suboptimal care in these areas, we believe that it is appropriate to develop these measures even though they capture relatively lower frequency, but important events. It is our goal to ensure that all hospice patients and families are receiving high quality of care and having their needs met.

Comment: In the context of both high priority measure areas, several commenters expressed concerns that these measure areas are more suitable as utilization measures rather than quality measures. For example, several commenters stated that performance measures should not be implemented as a means to discourage or correct undesirable organizational practices. Several commenters noted that information about these two measure areas is available via Program for Evaluating Payment Patterns Electronic Report (PEPPER) reports. While some believed Hospice PEPPER reports, alone, were sufficient to monitor access to levels of hospice care and potentially avoidable hospice care transitions, others felt that information from the PEPPER report is distinct from information provided by the quality measurement areas, and that the two quality measure areas thus represent value-added for the HQRP and providers.

Response: We appreciate commenters' comments regarding the distinction between utilization indicators and quality measures and similarities between the two high priority measure

[17] Wang S–Y, Aldridge MD, Gross CP, et al. Transitions Between Healthcare Settings of Hospice Enrollees at the End of Life. Journal of the American Geriatrics Society. 2016;64(2):314–322.

[18] Stevenson DG, Grabowski DC, Keating NL, et al. Effect of ownership on hospice service use: 2005–2011. J Am Geriatr Soc. 2016 May;64(5):1024–31. doi: 10.1111/jgs.14093. PMID: 27131344.

[19] Teno JM, Gozalo PL, Bynum JP, et al. Change in end-of-life care for Medicare beneficiaries: site of death, place of care, and health care transitions in 2000, 2005, and 2009. JAMA. 2013 Feb 6;309(5):470–7. doi: 10.1001/jama.2012.207624. PMID: 23385273.

[20] Aldridge MDP, MBA; Epstein, Andrew J. Ph.D.; Brody, Abraham A. RN, Ph.D.; Lee, Eric J. MPH; Cherlin, Emily Ph.D., MSW; Bradley, Elizabeth H. Ph.D. The Impact of Reported Hospice Preferred Practices on Hospital Utilization at the End of Life Medical Care. 2016;54(7):657–663.

[21] Wang S–Y, Aldridge MD, Gross CP, et al. Transitions Between Healthcare Settings of Hospice Enrollees at the End of Life. Journal of the American Geriatrics Society. 2016;64(2):314–322.

[22] Carlson MDA, Herrin J, Du Q, et al. Impact of Hospice Disenrollment on Health Care Use and Medicare Expenditures for Patients With Cancer. Journal of Clinical Oncology. 2010;28(28):4371–4375.

[23] Teno JM, Bowman J, Plotzke M, et al. Characteristics of Hospice Programs With Problematic Live Discharges. Journal of Pain and Symptom Management. 2015;50(4):548–552.

[24] Prsic E, Plotzke M, Christian TJ, Gozalo P, Teno JM. A National Study of Live Hospice Discharges between 2000 and 2012. Journal of Palliative Medicine. 2016;19(9):987–990.

[25] Barclay, J., et al., Association of hospice patients' income and care level with place of death. JAMA Internal Medicine, 2013. 173(6): p. 450–456.

[26] Casarett, D., et al., Does Continuous Hospice Care Help Patients Remain at Home? Journal of Pain and Symptom Management, 2015. 50(3): p. 297–304.

[27] Holland JM, Keene JR, Kirkendall A, et al. Family evaluation of hospice care: examining direct and indirect associations with overall satisfaction and caregiver confidence. Palliat Support Care. 2015 Aug;13(4):901–8. doi: 10.1017/S1478951514000595. PMID: 24992378.

areas and PEPPER measures. We would like to clarify that quality measures are distinct from utilization indicators, such as those included in the PEPPER reports. Utilization measures report statistics on services provided and billed to Medicare, and have a primary goal of protecting the Medicare program. That said, certain practice areas may be related to the integrity of the Medicare program and have significant implications on patient and family care outcomes and experience. Developing quality measures around those areas is a more effective strategy to ultimately promote quality improvement. The two high priority measure areas described in this rule measure areas that have been shown in the literature to impact quality of care through some structure, process, or outcome of care.[28] [29] [30] [31] [32] [33] [34] [35] As such, these 2 measure concept areas have a direct link to quality of care. Each measure concept's relationship to quality of care is addressed in greater detail in section 7. Measure Concepts Under Consideration for Future Years of this final rule, on comments specific to the potentially avoidable hospice care transitions measure area, and the section on comments specific to the access to levels of hospice care measure area. We continue to solicit input from stakeholders, including a TEP, a hospice caregiver workgroup, and a clinical user's panel to supplement evidence of this link in the literature.

Comment: Regarding measurement priority area 1 (Potentially Avoidable Hospice Care Transitions), many commenters agreed that care transitions at the end of life can be burdensome for patients and families. They noted that transitions out of hospice can often be prevented through diligent symptom management, patient and family education, and other aspects of care delivered by the hospice during the patient's stay. Thus, many of these commenters supported the importance of this measure area and its relationship to quality of care. Several commenters, including MedPAC, supported a measure related to potentially avoidable hospice care transitions. Others expressed concerns regarding potential measure specifications but were generally supportive of the concept. A few commenters recommended that CMS not pursue the development of this measure and shared their concerns.

Response: We thank the commenters for their support of a future HQRP measure related to potentially avoidable hospice care transitions. We also appreciate comments offering conditional support of the measure, with suggestions for how to define and specify this measure such that it meaningfully reflects hospice quality. These suggestions, in addition to the concerns of those who did not support continued development of this measure, are addressed in detail in the paragraph below.

Comment: In addition to the general comments regarding the limitations of claims data detailed earlier in the preamble, we also received comments expressing concerns about using claims as a data source for this measure area, specifically. Many commenters were concerned that patient and family needs and preferences are not captured in claims data and thus, the measure might penalize providers whose patients choose to disenroll from hospice. For example, commenters stated that patients may revoke the hospice benefit because they decide to pursue aggressive treatment for their terminal condition or to seek care from a hospital that is not contracted with the hospice. Several commenters noted that, even if a hospice provided adequate education to patients and families, they would still want to seek acute care for various reasons unrelated to the quality of care provided by the hospice. Several commenters emphasized that patients have the right to revoke the hospice benefit at any time and that these decisions are sometimes outside of the hospice's control. Commenters described other scenarios in which they believed that discharges from hospice and subsequent care transitions were outside the control of the hospice. For example, a few commenters mentioned payment and policy factors or local market-level factors that may trigger transitions from hospice to acute care. A few described instances in which a nearby hospital refuses to contract with them for providing GIP care, forcing them to discharge patients should they need GIP care. Several commenters believed that claims did not provide sufficient information to adequately reflect hospice practice. Specifically, commenters were concerned with using claims data to identify potentially avoidable hospice care transitions or distinguish between appropriate and inappropriate live discharges. Commenters discussed the situation in which a patient's clinical condition improved as an example of an appropriate live discharge. Several commenters requested that CMS provide examples of potentially avoidable hospice care transitions. Lastly, commenters suggested that claims data be supplemented with other data sources, such as the HEART tool in the future, in order to provide that contextual information necessary to determine whether a transition was appropriate or indicative of poor quality provided by a hospice.

Response: As previously stated, we acknowledge the limitations of claims data in capturing this information and would also like to clarify that this measure is not intended to determine whether each individual care transition or live discharge is appropriate. Instead, the measures will present provider-level rates of the process and outcome in the two proposed measure areas, comparing providers to their peers with relevant and available patient-level and hospice-level factors taken into account. Given the limitations of claims data to measure this area, we are examining information about care patterns and subsequent outcomes that are available in claims data to identify transitions that might be reflective of suboptimal quality provided by a hospice during a patient's stay (that is, failure to meet the needs of patients and their families). These transitions represent disruptions in continuity of care at a time when patients and families are extremely vulnerable. We agree that patient and family needs and preferences are an important factor in determining whether a hospice provider should be held accountable for a care transition and the related outcomes and that this information is not fully captured in claims data. However, research has demonstrated provider- and state-level

[28] Aldridge MDP, MBA; Epstein, Andrew J. Ph.D.; Brody, Abraham A. RN, Ph.D.; Lee, Eric J. MPH; Cherlin, Emily Ph.D., MSW; Bradley, Elizabeth H. Ph.D. The Impact of Reported Hospice Preferred Practices on Hospital Utilization at the End of Life Medical Care. 2016;54(7):657–663.

[29] Wang S–Y, Aldridge MD, Gross CP, et al. Transitions Between Healthcare Settings of Hospice Enrollees at the End of Life. Journal of the American Geriatrics Society. 2016;64(2):314–322.

[30] Carlson MDA, Herrin J, Du Q, et al. Impact of Hospice Disenrollment on Health Care Use and Medicare Expenditures for Patients With Cancer. Journal of Clinical Oncology. 2010;28(28):4371–4375.

[31] Teno JM, Bowman J, Plotzke M, et al. Characteristics of Hospice Programs With Problematic Live Discharges. Journal of Pain and Symptom Management. 2015;50(4):548–552.

[32] Prsic E, Plotzke M, Christian TJ, Gozalo P, Teno JM. A National Study of Live Hospice Discharges between 2000 and 2012. Journal of Palliative Medicine. 2016;19(9):987–990.

[33] Barclay, J., et al., Association of hospice patients' income and care level with place of death. JAMA Internal Medicine, 2013. 173(6): p. 450–456.

[34] Casarett, D., et al., Does Continuous Hospice Care Help Patients Remain at Home? Journal of Pain and Symptom Management, 2015. 50(3): p. 297–304.

[35] Holland JM, Keene JR, Kirkendall A, et al. Family evaluation of hospice care: examining direct and indirect associations with overall satisfaction and caregiver confidence. Palliat Support Care. 2015 Aug;13(4):901–8. doi: 10.1017/S1478951514000595. PMID: 24992378.

variation in proportion of hospice users experiencing care transitions, which signifies that market factors and hospice characteristics (that is, factors other than patient/family needs and preferences) influence transitions. We also agree that there are situations in which live discharges may be appropriate—for example, when a patient's clinical condition improves and they are no longer deemed to have a prognosis of 6 months or less. This measure area is not intended to suggest that live discharge is inappropriate for any individual patient but rather, to identify hospices with substantially higher rates of live discharges followed by either death or acute care use during a short period of time. Substantially higher rates of live discharge with these subsequent outcomes may indicate that providers are not meeting patient needs, signaling poor quality.[36]

In response to commenters' requests that we provide examples of potentially avoidable hospice care transitions, we would like to reiterate that this measure is currently in development and thus, its specifications have not yet been finalized. As previously stated, this measure is intended to address lack of continuity of care during a vulnerable time for patients and families. Thus, measure specifications will focus on live discharges from hospice followed by either death or acute care use during a short period of time. We will continue to carefully examine patterns of care for live discharge and consider them in measure development. We will continue to solicit and consider stakeholder input before finalizing measure definitions and specifications. The public will have the opportunity to comment on proposed measures and their specifications if and when these measure concepts are proposed in future rulemaking cycles.

Comment: Commenters offered suggestions for how to specify a measure examining potentially avoidable hospice care transitions. Several commenters recommended that CMS to look at live discharge followed by readmission to hospice, hospitalization, or death within a short time frame. One commenter suggested incorporating data elements from providers transferring patients to hospice. Several commenters cautioned against setting a benchmark for acceptable rates of live discharge.

Response: This measure is currently under development so its specifications have not yet been finalized. We appreciate the commenters' suggestions and will continue to take stakeholder input into consideration before finalizing measure specifications. This measure is intended to address lack of continuity of care by assessing transitions that may reflect poor quality on the part of the hospice. Thus, in line with the suggestions of commenters, measure specifications will focus on live discharges from hospice followed by either death or acute care use during a short period of time. We will carefully examine patterns of care for live discharge and consider them in measure development. We also appreciates commenters' concerns regarding the identification of a threshold or benchmark for this measure area. We acknowledge that some live discharges and care transitions are to be expected and appropriate, and agree that a threshold should not be set initially without careful analysis of national data and measure trends. We will also continue to engage stakeholders and conduct analyses to inform the specifications of this measure.

Comment: Several commenters questioned the relationship between this high priority measure and quality.

Response: We appreciate the commenters' concerns regarding this measure area's relationship to quality of care. The linkage between potentially avoidable hospice care transitions and outcomes for patients and families is demonstrated in the literature [37] [38] [39] [40] [41] with evidence suggesting that substantially higher rates of live discharge may signal poor quality.[42] For example, failures on the part of the hospice in advanced care planning, symptom management, responsiveness, and family education could drive patients and families to seek acute care. Furthermore, stakeholders support the importance of this measure and its relationship to quality. Overall, TEP members agreed on the importance of this measure concept and supported its continued development and future implementation. In addition, input solicited from hospice patients and caregivers suggests that this measure concept is important and meaningful to patients and families.

Comment: In addition to the general concerns regarding public reporting of the two high priority measure areas, we received a few comments specific to public reporting of the potentially avoidable hospice care transitions measure area. One commenter expressed concerns regarding hospice provider access to information that would enable them to internally monitor their performance on this measure (that is, claims for acute care stays occurring after hospice live discharge; information allowing them to compare their performance on this measure to the performance of other hospices). They recommended CMS to refrain from public reporting until hospice providers have access to this information.

Response: We appreciate the commenter's concerns regarding the ability of hospice providers to internally monitor their performance in this measure area. Though this measure would consider patient care transitions after hospice discharge, the intention is to capture performance gaps during the hospice stay that leads to the risk of transition. Thus, hospice's provision of high quality care during a patient's hospice stay should minimize the risk of those transitions. For example, adequate symptom management and responsiveness on the part of the hospice might prevent unnecessary transitions from occurring. Though hospice providers might not have access to claims from acute care stays occurring after they discharge a patient alive, this should not affect their ability to take steps to ensure the provision of high quality care to prevent these transitions and thus, should not affect their ability to perform well on this measure. Before the onset of any public reporting for any new quality measure, we provide confidential feedback reports (that is, Certification and Survey Provider Enhanced Reports (CASPER) Quality Measure (QM) reports, confidential to the extent permissible by federal law) to providers that allow them to compare their performance to national averages.

[36] MedPAC, Report to the Congress: Medicare Payment Policy. March 2017. *http://www.medpac.gov/docs/defaultsource/reports/mar17_medpac_ch12.pdf?sfvrsn=0.*

[37] Aldridge MDP, MBA; Epstein, Andrew J. Ph.D.; Brody, Abraham A. RN, Ph.D.; Lee, Eric J. MPH; Cherlin, Emily Ph.D., MSW; Bradley, Elizabeth H. Ph.D. The Impact of Reported Hospice Preferred Practices on Hospital Utilization at the End of Life Medical Care. 2016;54(7):657–663.

[38] Wang S–Y, Aldridge MD, Gross CP, et al. Transitions Between Healthcare Settings of Hospice Enrollees at the End of Life. Journal of the American Geriatrics Society. 2016;64(2):314–322.

[39] Carlson MDA, Herrin J, Du Q, et al. Impact of Hospice Disenrollment on Health Care Use and Medicare Expenditures for Patients With Cancer. Journal of Clinical Oncology. 2010;28(28):4371–4375.

[40] Teno JM, Bowman J, Plotzke M, et al. Characteristics of Hospice Programs With Problematic Live Discharges. Journal of Pain and Symptom Management. 2015;50(4):548–552.

[41] Prsic E, Plotzke M, Christian TJ, Gozalo P, Teno JM. A National Study of Live Hospice Discharges between 2000 and 2012. Journal of Palliative Medicine. 2016;19(9):987–990.

[42] MedPAC, Report to the Congress: Medicare Payment Policy. March 2017. *http://www.medpac.gov/docs/defaultsource/reports/mar17_medpac_ch12.pdf?sfvrsn=0.*

Comment: Several commenters were concerned that this measure may result in unintended consequences for patients and families. For example, a few commenters worried that it may encourage providers to approach care decisions with less attention towards patient and family wishes.

Response: We appreciate commenters' concerns regarding potential unintended consequences of a measure examining potentially avoidable hospice care transitions. With the development of any new quality measures, it is a priority of CMS to minimize any potential unintended consequences. Thus, we will work closely with the hospice industry and other stakeholder groups to ensure that this measure does not inadvertently impede a patients' choice to make a desired transition or have any other unintended consequence.

Comment: Regarding measure development priority area 2 (Access to Levels of Hospice Care), most commenters, including MedPAC, supported the ''access to levels of hospice care'' measure area. Several commented on its potential to encourage providers to better meet the needs of patients and families as well as its potential usefulness for Medicare beneficiaries and their families. Some commenters, though they had concerns with potential specifications for this measure, generally agreed that access to levels of hospice care is an important aspect of hospice care for patients and families.

Response: We thank the commenters for their support of a future HQRP measure related to access to levels of hospice care. We also appreciate comments offering conditional support of the measure, with suggestions for how to define and specify this measure such that it meaningfully reflects hospice quality. These suggestions are addressed in detail in the paragraph below.

Comment: In addition to the general comments regarding the limitations of claims data detailed above, we also received comments expressing concerns about using claims as a data source for this measure area, specifically, commenters noted that claims data would not provide information about when higher intensity levels of hospice care were needed, such as information about patient acuity. One commenter stated that claims data would not reflect situations in which GIP or CHC were offered but refused by patients and families. Several commenters were concerned that claims data would not reflect instances in which a patient didn't receive a higher intensity level of care because the hospice was able to get their symptoms under control without escalating the patient to GIP or CHC. A few commenters worried that their performance on this measure might be lower because their hospices focused on preemptively mitigating the need for higher intensity levels of care through diligent symptom management and patient and family education. Some commenters cautioned against judging access to and availability of GIP and CHC by delivery of such care. Several commenters suggested linking claims data with survey data that demonstrates a hospice's ability to provide higher intensity levels of care (for example, contracts with inpatient facilities).

Response: We agree that patient and caregiver needs and preferences for certain levels of care can impact the use of more intensive levels of hospice care and recognize that claims only provide information about what level of care was provided, not what level of care was needed or desired. However, research has demonstrated provider- and state-level variation in proportion of hospice users receiving higher intensity levels of hospice care, which signifies that market factors and hospice characteristics (that is, factors other than patient/family needs and preferences) influence GIP and CHC provision. This measure concept is not intended to suggest that a higher intensity level of care is appropriate or needed for any given individual; the purpose of this measure concept is to ensure that patients and families have access to these higher intensity levels of care if needed. Furthermore, there will be risk adjustment for this measure, which will statistically account for patient case-mix differences across hospices so that the outcome rates can be more accurately compared despite the differences in patient case-mix. We acknowledge the limitations of claims data and thus, the inability to control for certain relevant factors such as patient and family preferences and refusal of care. However, these factors tend to distribute evenly across hospices. In other words, each hospice may serve patients and families with varying level of preference for higher intensity levels of hospice care. As such, the inability to control for these factors does not necessarily disadvantage certain hospices. We encourage hospice providers to take measures to preemptively meet the symptom management and other needs of patients and applaud those who are doing so. However, we also recognize that there will be instances in which, despite a hospice's best efforts, certain patients will require higher intensity levels of hospice care. The focus of this measure area is to ensure that these patients have access to the care that they need, and to encourage hospices to continually assess patients and provide different levels of care as needed. We also thank commenters for their suggestions regarding supplementing claims data with other data sources. We will consider the benefit of doing such in the context of the potential burden associated with data collection and measure calculation and reporting. We will also consider opportunities to incorporate other data sources into future HQRP measure development efforts.

Comment: Several commenters cautioned against setting a threshold or benchmark for GIP and CHC provision in the absence of evidence regarding where this threshold should lie.

Response: We appreciate the commenters' concerns regarding the identification of a threshold or benchmark for this measure area. We agree that thresholds should not be set arbitrarily, without rigorous information gathering and measure testing. We will continue to engage stakeholders and conduct claims data analyses to inform the specifications of this measure.

Comment: Several commenters questioned the relationship between this high priority measure area and quality.

Response: This measure area's relationship with quality of care is supported by the literature. Appropriate use of CHC and GIP increases the likelihood of a hospice patient dying in his or her location of choice, decreases health resource utilization resulting in potential cost savings, and increases patient and caregiver satisfaction.[43] [44] [45] This linkage between appropriate use of higher intensity levels of hospice care and outcomes for patients and families is further supported by a technical expert panel and other stakeholder groups thus far engaged in the development of this measure. Overall, TEP members agreed on the importance of this measure concept and supported its relationship to quality. Additionally, input solicited from hospice caregivers has suggested that this measure concept

[43] Barclay, J., et al., Association of hospice patients' income and care level with place of death. JAMA Internal Medicine, 2013. 173(6): p. 450–456.

[44] Casarett, D., et al., Does Continuous Hospice Care Help Patients Remain at Home? Journal of Pain and Symptom Management, 2015. 50(3): p. 297–304.

[45] Holland JM, Keene JR, Kirkendall A, et al. Family evaluation of hospice care: examining direct and indirect associations with overall satisfaction and caregiver confidence. Palliat Support Care. 2015 Aug;13(4):901–8. doi: 10.1017/S1478951514000595. PMID: 24992378.

is important and meaningful to patients and families.

Comment: Several commenters expressed concern with the feasibility of certain hospices providing all four levels of care and described factors that may lower their performance on a measure examining access to higher intensity levels of hospice care. For example, some commenters discussed staffing challenges associated with providing CHC and GIP, particularly for smaller hospices. Several commenters noted challenges related to the CHC billing requirement that at least 8 hours of continuous care be provided within one calendar day. They described situations in which the continuous care they are providing is not reflected as CHC in claims data because it did not meet the 8 hour threshold within 1 calendar day. Others described market factors influencing a hospice's ability to provide GIP, including issues with contracting with nearby hospitals.

Response: While we acknowledge that some hospice providers may face unexpected challenges in providing higher intensity levels of hospice care, according to the Hospice Conditions of Participation (CoPs) all hospice agencies regardless of size, location or other organizational or market characteristics must be able to provide all four levels of hospice care. We will continue to discuss these issues with a technical expert panel and other stakeholder groups and conduct analyses to better understand sources of variation in GIP and CHC provision across hospices. These discussions and analyses will inform the specifications for this measure. Though we do acknowledge the challenges that commenters raised, it is our expectation that all hospices meet the requirements set forth in the Hospice (CoPs) and demonstrate the capacity to meet the needs of patients and families.

Comment: A few commenters expressed concerns with the access to levels of hospice care measure promoting overutilization of GIP and CHC. They added that the intent of this quality measure conflicts with efforts to discourage overutilization of these higher intensity, more costly levels of hospice care.

Response: We appreciate these commenters raising one potential unintended consequence of this measure area. It is our goal to minimize the unintended consequences of any new quality measure. The purpose of this measure area is not to encourage GIP or CHC for any individual patient or to encourage very high rates of GIP or CHC use within hospices. Rather, the focus of this measure area is to assess whether patients have access to these levels of care if they need it, and to encourage hospices to continually assess patients and provide different levels of care as needed. With that said, we will provide educational opportunities for providers and the public to clearly explain the intent of this measure and its relationship to quality of care. Provider education will emphasize that the purpose of this measure is to promote access, not to encourage increased use of GIP or CHC for any given patient. We will also coordinate this measure and relevant utilization measures reported under the PEPPER to design a balanced incentive for hospices to provide the level of GIP and CHC care to meet patient and family needs.

Comment: In addition to offering comments about the two high priority measure development areas, several commenters stated their general support for future HQRP measure development efforts. Commenters noted the importance of developing quality measures that reflect the holistic and comprehensive care provided by hospice and measures that recognize that the unit of hospice care is composed of both the patient and their family. Several commenters recommended CMS to turn attention towards the development of outcome measures for the HQRP to supplement current measures, many of which are process measures. Additionally, several commenters recommended CMS to ensure that all future measures are clearly defined and undergo rigorous testing prior to implementation in the HQRP. Commenters emphasized the importance of stakeholder engagement in all measure development efforts. Several commenters specifically noted the importance of patient and family engagement to develop new HQRP measures, including measures that capture patient experience. Several commenters suggested that CMS engage with NQF and the MAP in determining priority areas for future measurement. One commenter pointed specifically to the PEACE Project, a CMS project that developed a set of quality measures, with complete specifications, and data collection tools for use by hospice and palliative care providers in quality improvement, and the 2012 MAP Performance Measurement Coordination Strategy for Hospice and Palliative Care as resources from which to pull measures and measure concepts.

Response: We thank the commenters for their support and suggestions for future quality measurement efforts as part of the HQRP. We agree that quality measures should capture the aspects of care that set hospice apart from many other types of care, including the provision of holistic interdisciplinary care and the recognition of both the patient and their family as the unit of care. Further, we agree with commenters that the development of outcome measures should be prioritized in future HQRP measure development. It is our goal to supplement existing HIS and CAHPS® measures to develop a more comprehensive measure set that captures key domains of hospice care. With the development of any new QRP measure, we follow a rigorous process for measure development which includes measure conceptualization, measure specification, and measure testing prior to measure implementation. Each of these stages of development incorporates ample opportunity for stakeholder engagement. We consider the perspective of clinicians, patients and caregivers, and other stakeholder groups integral to the development process. We will continue to engage with the NQF and the MAP to identify priority measure concepts. We would like to note that all measures undergo review by the MAP prior to implementation in the HQRP. Further, where possible, CMS seeks NQF endorsement for any new HQRP measures that are not already endorsed by NQF. For more details regarding our measure development process, please refer to the Blueprint for CMS Measures Management System Version 13: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/MMS-Blueprint.html*.

Comment: Commenters offered suggestions for future measure concepts to consider for implementation in the HQRP including:

- Congruence of place of death and patient wishes;
- Psychological, psychiatric, and psychosocial aspects of care;
- Spiritual well-being;
- Bereavement services offered by a hospice;
- Volunteer services offered by a hospice;
- Occupational therapy outcomes;
- Provider commitment to credentialing their staff;
- Care planning (for example, regular review of patient and family goals; shared decision making);
- Timely communication of patient's goals across all providers;
- Cost of care; and
- Care coordination among providers.

In addition, commenters suggested measures specific to certain subpopulations of hospice patients including:

- Pediatric patients;

• Patients with a diagnosis of Alzheimer's or Dementia;
• Patients with a short length of stay; and
• Patients receiving hospice care in a nursing facility or assisted living facility.

Response: We thank the commenters for their suggestions regarding potential future quality measures. We agree that these are important areas of hospice and will consider these suggestions in future HQRP measure development efforts.

8. 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. 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, 2017, that provider will begin submitting HIS data for patient admissions occurring after November 5, 2017. 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 2019 APU, which is associated with patient admissions occurring January 1, 2017 through December 31, 2017).

This policy allows us 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, we finalized that new hospices begin collecting HIS quality data beginning on the date noted on the CCN notification letter. We believe this policy provides 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 our policy requirements for new providers with the functionality of the HIS data submission system (QIES ASAP).

c. Previously Finalized Data Submission Mechanisms, Timelines, and Deadlines

In the FY 2015 Hospice Wage Index final rule (79 FR 50486), we finalized our policy requiring that hospices 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.9.b through III.C.9.c of the FY 2015 Hospice final rule (79 FR 50486) 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 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. 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-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.

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 us 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), we 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), we 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 after the Event Date for HIS Admission records and 7 days after 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, we will continue 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 CMS HQRP Web site, listserv messages via the Post-Acute Care QRP listserv, MLN Connects® National Provider Calls & Events, MLN Connects® Provider eNews and announcements on Open Door Forums and Special Open Door Forums.

The comment and our response are below.

Comment: We received a few comments on the previously finalized data submission mechanism, the HIS. One commenter offered several suggestions for potential revisions to the HIS V2.00.0, including suggested edits to items in Section A and Section J of the HIS-Admission record. The commenter offered suggestions for response options or items that could be potentially eliminated, and offered suggestions for refinements to coding guidance provided in the HIS Manual for these items. Another commenter requested CMS include additional examples in the HIS Manual; specifically, examples that had greater clinical relevance for a broader range of hospice providers.

Response: The HIS V2.00.0 was previously proposed and finalized as a data collection mechanism for the HQRP. We refer readers to the FY 2017 Hospice Wage Index final rule (81 FR 52167 through 52192) for a detailed discussion of the HIS V2.00.0. We invite the public to submit questions or suggestions about previously finalized and currently implemented proposals through sub-regulatory communication channels, including the Hospice Quality Help Desk at *HospiceQualityQuestions@cms.hhs.gov*, and through other communication channels such as Open Door Forums and Special Open Door Forums. These can be found at the CMS Web site: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Hospice-Quality-Reporting/Spotlight.html*. Requests such as including additional examples in the HIS Manual can be addressed at the Hospice Quality Help Desk. We are always seeking ways to make the HIS Manual more user-friendly and will consider adding examples that provide more clinical relevance for a broader range of hospice providers. By writing to the Hospice Quality Help Desk, we can communicate to be sure we understand the issue to most appropriately address it.

d. New Data Collection and Submission Mechanisms Under Consideration: Hospice Evaluation & Assessment Reporting Tool (HEART)

We have 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, we have established the HQRP, which includes clinical quality measures from the HIS and patient experience of care measures from the CAHPS® Hospice Survey. We have also 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 discussed in the FY 2017 Hospice Wage Index final rule (81 FR 52177), to facilitate continued progress towards the requirements set forth in section 3004 of the Affordable Care Act, we are in the early stages of the development of a new data collection mechanism for use by hospices. This new data collection mechanism would be a hospice patient assessment tool, which would serve two 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. In the FY 2017 Hospice Wage Index final rule (81 FR 52143), we solicited input from the public on the development of a hospice patient assessment tool that would collect quality, clinical, and other data with the ability to be used to inform future payment refinement efforts. Overall, feedback from the public was supportive of the move towards a standardized patient assessment instrument, and commenters offered some guiding principles for CMS to keep in mind in the development of a patient assessment tool, given the unique nature of hospice care. For a detailed discussion of the public comments and responses, as well as our guiding principles and motivation behind the development of a hospice patient assessment tool, we refer readers to the FY 2017 (81 FR 52143). As noted in the FY 2017 Hospice Wage Index final rule, we envision 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 also 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 and comprehensive assessment), but would be designed to complement data that are collected as part of high-quality clinical care. The new data collection effort would replace the current HIS, but would not replace other HQRP data collection efforts (that is, the CAHPS® Hospice Survey), nor would it replace regular submission of claims data. We envision 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.

We did not propose a hospice patient assessment tool at this time; we are still in the early stages of development of an assessment tool to determine the appropriate content and feasibility of such a tool. As such, we have made progress over the past year in the development of a hospice patient assessment tool, preliminarily called the Hospice Evaluation & Assessment Reporting Tool (HEART). CMS's measure development contractor, RTI International, has begun preliminary HEART development activities, including: Conducting environmental scans and engaging clinical experts to determine which domains of care are important to capture in a hospice patient assessment; posting a national provider call and forming a Clinical Committee comprised of hospice organizations from across the United States to participate in the early development of an assessment; and collaborating within CMS to assess various stakeholder needs and encourage collaboration within CMS and across other HHS agencies. As we move forward with the development of the HEART patient assessment tool, we will continue to keep the public informed of our progress and solicit input as we establish and finalize domains of care to include in the assessment, and as we move towards specific item wording and development. Once we move past the preliminary phases of development and conceptualization, we will communicate a timeline for the HEART development, testing, and proposed implementation in future rulemaking cycles.

As mentioned in the FY 2017 Hospice Wage Index final rule (81 FR 52143), it is important for CMS to develop a hospice patient assessment tool that is scientifically rigorous and clinically appropriate for the hospice population, thus we believe that continued and transparent involvement of stakeholders is critical. We will continue to receive stakeholder input from MedPAC and ongoing input from the provider community, Medicare beneficiaries, and technical experts. Additionally, it is important for CMS to minimize data collection burden on providers in the development of HEART. We will ensure that hospice patient assessment data items are not duplicative or overly burdensome to providers, patients, caregivers, or their families. We will also work with the public and other stakeholders to ensure that HEART takes into account the unique aspects of hospice care delivery including symptom burden and psychosocial needs, patient and family preferences, care of imminently dying patients, and the complexity of providing hospice care in multiple settings and at multiple intensity levels.

The comments and our responses are set forth below.

Comment: Many commenters were supportive of the continued development of a patient assessment tool, HEART. Commenters believed that—beyond currently available CMS data sources—a tool such as HEART would enable a broader picture of the quality of care provided by hospice agencies, as well as a more comprehensive picture of patient need and service delivery. Commenters also agreed with CMS that this enhanced patient assessment tool could be useful for quality purposes and potential payment purposes. MedPAC supported HEART, noting that a patient assessment instrument would gather more detailed clinical information on hospice patients (for example, patients' symptom burden), facilitate the development of more meaningful quality measures, and be helpful for payment policy purposes. Many commenters offered their support to CMS in the development of HEART, noting that transparent involvement of stakeholders would be crucial for ensuring HEART is scientifically rigorous, clinically appropriate, addresses the needs of individual patients, and sets the foundation for data collection that more accurately reflects the needs of patients served. In addition to voicing general support for HEART, commenters also offered several suggestions and considerations for CMS to keep in mind as we move forward with the development of HEART. Suggestions focused on the following themes: Intended use of HEART, Content of HEART, Processes for HEART development, HEART Policies and Procedures, and Burden. Beyond these major themes, commenters also offered suggestions for HEART's relationship to quality and payment and cross-setting considerations.

Response: First, we thank commenters for their support of the development of a patient assessment tool, HEART. We agree that enhanced data collection would further the goals of the HQRP and the Medicare Hospice Benefit by providing data that could be useful for development of future quality measures and potential future payment refinements. Second, we appreciate the input and recommendations from the hospice community. The input received from commenters are invaluable as we move forward with the development of HEART; we look forward to continued collaboration with our stakeholders and the hospice community. We address specific comments received in greater detail in paragraph below.

Comment: CMS received a few comments regarding the utility of HEART and CMS's vision for how HEART would be used for quality and payment purposes. A couple of commenters recommend CMS to ''move cautiously'', particularly in the area of payment refinement. One commenter suggested that CMS make a concerted effort to—in future rulemaking cycles—separate payment refinements from the expanded quality data that HEART would offer.

Response: We would like to take this opportunity to further clarify our vision for HEART and HEART's ultimate utility. At this time, we envision HEART as a patient assessment tool that would replace the HIS. HEART would provide richer data to offer a broader, more comprehensive picture of quality of care received by hospice patients and their families. We believe HEART may provide data that could inform future payment refinements, we would like to clarify that HEART's role in future payment refinements is not definite. We realize that before a patient assessment can be used for payment purposes, it must undergo rigorous testing to investigate whether data items are reliable and valid predictors of resource utilization. We acknowledge and appreciate that extensive testing of HEART data items will need to occur before we can make a final determination about whether HEART will prove useful in informing future payment refinements. This analysis would be in addition to the analyses that will be conducted to determine the scientific soundness of the data items themselves, as well as in addition to analyses conducted to inform the development of future quality measures. Thus, at this time, we cannot say definitively whether HEART will be used for payment refinements. Furthermore, any changes to the hospice payment methodology would be subject to the rulemaking process, which allows for public comment on any payment proposal. Although this is a potential use of the data, until extensive analysis and testing is conducted, we cannot make a final determination on the role HEART may play in future payment refinements. We would also like to take this opportunity to reassure the public of our timeline for development and testing of HEART. We appreciate the need to use a rigorous process in the development of testing and HEART; we assure the public that we will work on a timeline that allows for iterative testing and refinements, and provides ample opportunity to solicit the feedback of technical experts and the hospice community. Further details on our timeline and processes for development and testing of HEART are discussed further on in the preamble.

Comment: Many commenters offered recommendations on the content of HEART. Many commenters noted the unique nature of hospice care and offered considerations for designing HEART to ensure it would reflect the comprehensive and holistic aspects of hospice care. Specifically, commenters recommended that CMS ensure HEART: (1) Reflects the holistic and comprehensive nature of hospice care, including physical, psychosocial, and spiritual components; (2) recognizes the importance of an individualized approach to care; (3) includes the patient and family's right to refuse or defer offered services; (4) accommodates the delivery of care in various settings, including nursing homes, assisted living facilities, hospitals, hospice facilities, and the patient's home; and (5) recognizes that the assessment must be interdisciplinary. These commenters also encouraged CMS to ensure that data gathered through HEART is easily and readily usable for development of and updates to the plan of care. In addition to accommodating the facets of care noted above, a few commenters discussed the importance of ensuring flexibility in HEART to accommodate care of the imminently dying patient. Commenters noted that patients who are imminently dying at the time of admission to hospice need the hospice to immediately address high priority patient and family needs; completing assessment forms such as HEART could interfere with providing immediate clinical and psychosocial support for vulnerable patients and families who are facing imminent death. One commenter believed that requiring completion of all HEART data elements, regardless of patient status, would obligate hospices to complete regulatory requirements at the expense of addressing urgent patient and family needs for patients who are close to death upon admission to hospice. This commenter believed hospices should have the discretion to complete only those aspects of assessment that are most critical to the needs of the patient and family, and that to promote this discretion, CMS should allow flexibility in completing HEART items for these patients. CMS received a couple of comments regarding the inclusion of standardized tools in HEART. One commenter was supportive of including validated, standardized instruments in HEART (for example, standardized pain scales, symptom management assessment tools). This commenter believed that the inclusion of standardized tools would reduce duplication with assessments that hospices already complete as part of usual care. On the other hand, another commenter cautioned against prescribing the use of specific validated, standardized tools. This commenter believed that it would be important for CMS to preserve the integrity of the hospice philosophy by allowing hospice clinicians to individualize assessments and care based on clinical judgment, and that prescribing specific standardized tools may restrict clinical judgment and practice. One commenter recommended including HEART data elements that would capture social risk factors. Another commenter suggested CMS to include patient preferences in HEART data elements.

Response: We appreciate commenters' considerations on what should be included in the content of HEART. We wholeheartedly agree with commenters regarding the unique nature of hospice care, and we will continue to keep the hospice philosophy as the foundation of the HEART patient assessment. We seek to develop an assessment that reflects the distinctive aspects of hospice care, including the team-based, multi-disciplinary approach that is essential to hospice. We agree with the points raised by commenters about the overall focus of HEART and aims to develop a tool that addresses the holistic nature of hospice, incorporating medical, psychosocial, spiritual, and other aspects of care that are important for patients and their caregivers. We also appreciate commenters' specific suggestions regarding 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 patients who are imminently dying, patients' and caregivers' right to decline services or treatment, and the fact that hospice is delivered in multiple settings. We appreciate commenters' suggestions about including items to capture other important facets of care, including suggestions about the inclusion of standardized tools, the suggestion to incorporate patient preference into HEART, and the suggestion to consider data collection on social risk factors. We will keep these considerations in mind as we move forward with HEART development.

Comment: CMS received many suggestions from commenters regarding the process for continued development of HEART. All of these commenters encouraged CMS to engage stakeholders and the hospice community in the development process, and appreciated CMS's commitment to a transparent and collaborative development process. Commenters believed that extensive stakeholder engagement would lead to meaningful data that is truly reflective of quality of care delivered by hospices. Due to the magnitude, complexity, and importance of HEART, one commenter encouraged CMS to go beyond traditional opportunities for input (for example, TEPs) and employ widespread

processes for gathering provider input. Another commenter encouraged CMS to broaden the definition of relevant stakeholders and include EMR vendors as a stakeholder in the HEART development process. This commenter believed that many of the difficulties encountered in implementation of new requirements stem from the complexity of integrating data collection into EMR systems, and that inclusion of EMR vendors in the development process may result in a smoother implementation of HEART. In addition to offering suggestions for stakeholder engagement, many commenters offered suggestions for testing and refinement of HEART. Several commenters encouraged CMS to use an iterative testing approach; commenters encouraged CMS to conduct several phased pilot tests, which would allow for the iterative and ongoing refinement of HEART. A few commenters recommended CMS include a range of hospice agencies in pilot tests, including hospices of varying sizes, locations, and organizational structure. One commenter asked if CMS could share any progress or materials on the development of HEART, such as the structure of the assessment. Finally, many commenters offered their support to CMS throughout the development process, volunteering to provide feedback and participate in pilot initiatives.

Response: We are appreciative commenters continued support and engagement throughout the development process; and we look forward to opportunities for continued collaboration and input. We have already begun to engage the public and other stakeholders in our development process. We have formed a Clinical Committee comprised of hospice organizations from across the United States, and we have begun conversations with hospice clinical experts and other stakeholders with CMS and across HHS. We look forward to continuing these discussions and engaging in additional opportunities for stakeholder input. We agree that input from the hospice industry will be invaluable and assure commenters that our process for development and testing of HEART will allow ample opportunity to refine and improve HEART based on stakeholder input. We plan to hold TEPs to inform the development, testing, and refinement of the patient assessment. We also plan to provide other opportunities for stakeholders to provide input through venues such as Special Open Door Forums and other regular HQRP communication channels. We will also consider additional mechanisms for soliciting input from the public to further enhance opportunities for input.

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. As with the development of patient assessment instruments in other care settings, tentative development processes may include holding TEPs to gather input from hospice clinicians and researchers, conducting small-scale pilot tests to determine feasibility of a patient assessment instrument for hospice, conducting a larger, national test to establish reliability and validity of items and determine appropriate use of each item, providing ongoing opportunities for input and engagement from the hospice community. Only after completion of a thorough development process over the next several years would CMS consider proposing HEART through rulemaking for implementation in the HQRP. We believe our tentative development process to be aligned with commenters' recommendations for a thorough and iterative testing approach, allowing ample opportunity for the refinement of HEART prior to implementation. Further details on HEART development and testing will be communicated in future rulemaking cycles and through sub-regulatory communication channels. We will also announce opportunities for stakeholder input and participation regularly through sub-regulatory communication channels (for example, MLN eNews ListServs, ODFs, SODFs). Regarding the commenter's request for information on the current draft version of HEART, we are still in the early, initial phases of HEART development; we look forward to sharing our progress with the provider community as developments become available.

Comment: Several commenters offered suggestions to CMS regarding policies and procedures for HEART data collection and submission, including feedback on data collection intervals, modes and timing for data collection and submission, and implementation of HEART. Commenters had differing opinions as to whether HEART data should be collected at admission and discharge only, or if data should be collected at additional interim time points beyond admission and discharge. Commenters who supported interim data collection efforts noted the importance of measuring care throughout a patient's stay to fully understand quality of care delivered to patients over the course of their length of stay. Commenters who supported admission and discharge data collection believed interim data collection efforts only would prove overly burdensome for providers. Regarding data completion and submission, one commenter encouraged CMS to implement data collection and submission timeframes that are reasonable and clear.

Several commenters offered suggestions regarding the implementation of HEART. Commenters encouraged CMS to provide advanced notice prior to any final implementation date in order to allow ample time for infrastructure and IT system development, as well as clinician training. Several commenters recommended CMS use a phased implementation or dry run approach, which would ensure adequate time (that is, at least 1 year) for EMR vendors to incorporate HEART into their software; for hospices to initiate and thoroughly test HEART data collection processes; and, to train staff and ensure competency in use. One commenter noted that issues experienced with the implementation of prior HQRP data collection efforts (for example, NQF #0209 measure) might have been alleviated with longer implementation and dry run periods. Several commenters underscored the importance of adequately training clinicians and other staff on HEART data collection, coding rules, and definitions to ensure accurate data collection. These commenters recommended CMS to provide ample and ongoing educational opportunities to support HEART implementation. Commenters encouraged CMS to include clear definitions for each data element included in HEART. These commenters believed that clear definitions that are readily understood are imperative to the success of any patient assessment data collection effort. One commenter noted that although CMS training materials for the HIS are thorough and comprehensive, proving useful for staff responsible for HIS data submission, the level of detail included in CMS materials is often too great for clinical staff. This commenter recommended that, in addition to providing traditional educational and training materials, CMS consider developing streamlined educational materials geared towards clinical staff. Finally, a few commenters touched on the information technology (IT) burden related to potential implementation of HEART. These commenters noted the

time and effort associated with upgrading EMR vendor systems and training staff on functionality of updated systems. One commenter recommended CMS to ''include sufficient protections for small hospices'' and keep in mind how IT burden affects these organizations. This commenter also suggested that CMS ensure new quality reporting requirements are tenable for small hospice programs, given their limited health IT resources.

Response: We appreciate commenters' input on processes and policies for HEART data collection and submission. We appreciate commenters' feedback on intervals for HEART data collection, as well as commenters' recommendations regarding data collection and submission timeframes, systems for data submission, and timeline for implementation of HEART. We agree that having data submission timeframes and policies that align with clinical workflow and are clear to providers is very important. We also agree that a longer or phased implementation approach could help facilitate a smooth transition to HEART and minimize burden, allowing ample time for upgrading IT and EMR systems, with minimal disruption of provider workflow and increased quality of data submitted. We also agree that educational materials and ample opportunity for training—including clear and understandable definitions for each data element—will be critical to the success of HEART. Finally, we understand and appreciate commenters' concerns about the complexity of upgrading EMR and IT systems to accommodate new data collection efforts. With respect to commenters' suggestions about clear and understandable definitions for each data element, our hope is that our phased, iterative pilot testing approach will offer rich information on how hospices interpret HEART data elements, yielding definitions that are reflective of the reality of hospice care and are readily understood by providers. Regarding commenters' concerns about health IT and the complexity of upgrading EMR systems, we understand the concerns about the time required for vendors to upgrade EMR systems and for hospices to be trained. In addition, we would like to note that we anticipate making data completion and submission software available to providers at no cost so that providers can complete and submit HEART data free of charge, without the need to purchase an EMR or vendor software. This would be analogous to the HART and QIES ASAP systems currently used for HIS data completion and submission.

Comment: Although commenters were generally supportive of HEART, many commenters cautioned CMS against the creation of a patient assessment that would be overly burdensome. Commenters applauded CMS's commitment to the development of a tool that is minimally burdensome and not duplicative. In their comments related to burden, commenters discussed the consideration of burden to the hospice provider, as well as potential burden to the patient and family. Commenters encouraged CMS to be cognizant of potential burden that additional data collection could place on patients and families. Commenters stated that the initial portion of a patient's stay in hospice is a time when clinicians and staff are developing a relationship with the patient and family and noted that in usual practice, hospices must balance the collection of important data necessary to deliver care with the need to not overwhelm the patient and family unit during this time. One commenter noted that this consideration is even more critical when caring for an imminently dying patient. This commenter believed that standardized data collection has the potential to be burdensome to the patient and family and delay initiation of timely care to address high priority needs. Commenters encouraged CMS to keep this balance in mind when developing HEART.

Regarding burden to the provider, commenters cautioned CMS against designing an assessment that would be overly burdensome for providers, noting that the move to a more comprehensive patient assessment would require investments in chart review and other data completion activities. One commenter recommended CMS to accurately account for any potential increases in burden and cost in calculations of burden and costs of regulatory impacts. Commenters mentioned collaboration with the provider community and efficiencies from EMR software as potential ways to reduce burden. One commenter raised the relationship between HEART and existing CoP requirements and. questioned how CMS envisioned this tool being minimally burdensome when CMS stated in the proposed rule that HEART would not replace initial or comprehensive assessment requirements.

Finally, several commenters noted the tradeoff between time spent on assessment tools and regulatory requirements and time spent delivering care and addressing patient and family needs. Commenters recommended CMS to ensure that HEART data elements are overall meaningful and contribute to care planning, and cautioned CMS against the creation of a patient assessment tool that would simply be an exercise in ''filling out forms'' and ''checking off boxes''. Commenters noted that time spent completing HEART would be time spent away from providing direct care and implored CMS to keep this tradeoff in mind in the development of HEART.

Response: We appreciate commenters concerns about burden of data collection efforts for both hospice providers and for hospice patients and their families. Regarding burden to patients and families, we agree with commenters that HEART should not impose burden on patients and families, especially during this early time in hospice care, and in instances where hospice patients are admitted close to death. It is our objective to ensure that HEART aligns with clinical practices so that collection of data for HEART poses no additional burden on patients and families beyond what hospices collect as part of usual care delivery. To ensure this objective is met, we will solicit clinician and patient and family caregiver input as part of HEART development process. Finally, we recognize the potential tradeoff between data collection and reporting requirements and time spent with the patient and family delivering care. CMS will keep this tradeoff at the forefront of HEART development to ensure that HEART does not detract from the primary mission of hospice care.

Regarding burden to hospice providers, we are not including HEART in this rule, so there is no additional burden associated with this rule. Once the HEART assessment has been tested and is proposed in rulemaking, CMS will provide a PRA package and burden estimates. As noted in this rule, the HEART assessment would replace the current HIS reporting requirement, meaning HEART would not represent an additional reporting requirement for hospices. Although HEART would not replace current CoP requirements for the initial and comprehensive assessment, CMS's intent is to design HEART in a way that is complementary to the initial and comprehensive assessment to minimize burden on providers. Similar to how CoP requirements for the initial and comprehensive assessment do not require hospices to use specific formats, we envision HEART having similar levels of flexibility for providers. We believe that a flexible patient assessment tool that allows for clinician judgment will help minimize burden

and duplication of existing requirements. Moreover, any patient assessment tool proposed through rulemaking would undergo OMB and PRA review and approval, the purpose of which is to ensure required data collection efforts do not impose undue burden on the public.

We will continue to collaborate with stakeholders and will ensure that any patient assessment is minimally burdensome and not duplicative. We consider the perspective of clinicians and patients, and caregivers integral to the development process and will provide ample opportunity for stakeholder input to ensure any assessment tool is clinically appropriate and minimally burdensome. Moreover, burden will be a focus of the pilot data collection efforts in order to ensure we are appropriately assessing burden of data collection.

Comment: CMS received a few comments about HEART's relationship to quality and payment, and what providers should or should not be held accountable for. With respect to HEART's relationship to quality and the development of future quality measures using HEART data, one commenter stated that CMS should not hold providers accountable for outcomes of care that are not feasible for all hospice patients. For example, the commenter felt that providers should not be held accountable or penalized for occurrence of skin wounds at the end of life because organ failure and skin breakdown is a normal part of the dying process. Similarly, the commenter also suggested CMS not hold providers accountable for decreases in function and activities of daily living since this is an expected trajectory among hospice patients. Finally, the commenter requested that CMS not hold providers to achieving complete symptom control because this is not feasible in all patients. Another commenter encouraged CMS to appropriately risk adjust any outcomes generated from HEART data to appropriately reflect patients' right to refuse services, short lengths of stay in hospice, and instances where attending physicians refuse to sign orders that align with the patient preferences. This commenter also encouraged CMS to capture preference-concordant care as an outcome measure in HEART.

Several commenters addressed HEART's relationship to resource utilization and payment, offering suggestions to CMS as to how assessment data might be useful for future payment refinements. One commenter discussed data that HEART would need to capture if CMS moved to a case-mix payment methodology. The commenter noted that hospices should be paid higher rates for patients needing higher levels of services, including patients who have pain or other symptoms that are difficult to manage, and patients with wounds who need higher levels of skilled care. The commenter suggested that CMS not set a payment rate lower than the rate hospices receive under current payment policy. MedPAC recommended CMS to ensure that elements of HEART were not unduly subject to provider manipulation if HEART data was to be used for payment purposes.

Response: We appreciate commenters' feedback and suggestions about HEART's relationship to quality. We will take these suggestions into consideration for future rulemaking and the continued development of HEART and any associated quality measures. We recognize and agree with the commenter that some outcomes of care are not achievable for dying patients and will work to ensure that any future outcome measures are appropriate for the hospice population. We also appreciate the commenter's suggestion to consider preference-concordant care as a future quality domain in HEART, as well as the suggestion to appropriately risk-adjust any future outcome measures generated from HEART data.

We also thank commenters for their suggestions regarding HEART's relationship to resource utilization and payment. As noted earlier in the preamble, we will need to complete extensive analysis before we determine what—if any—utility HEART will have for future payment refinements. That said, we recognize that resource utilization in hospice is unique and is most often linked to patient symptomology and service needs rather than diagnosis. As such, it is our paramount concern to develop a patient assessment tool that appropriately reflects the needs of patients and services provided by hospices to meet those needs. We will continue to involve stakeholders, including hospice organizations and clinicians, in the development process to ensure this objective is met. We also recognize the importance of developing patient assessment data elements that are scientifically rigorous and are not easily manipulated by providers. We will ensure that any data elements included in HEART undergo rigorous testing and validation prior to implementation.

Comment: Several commenters also discussed cross-setting issues with respect to HEART. Commenters suggested that CMS consider how HEART would fit in with efforts to develop other patient assessment instruments for other post-acute care settings (for example, IRFs, SNFs, home health, and LTCHs). Commenters encouraged CMS to balance the need between developing uniform and consistent post-acute care assessment tools that would include post-acute settings and hospice, with the need to ensure HEART is reflective of the unique aspects of hospice care. Although commenters recognized cross-setting standardization and coordination as an opportunity to develop cohesive patient assessments that enable better longitudinal plans of care and integration across the care continuum, commenters also stressed the importance of ensuring that HEART reflect the interdisciplinary and unique aspects of hospice care. One commenter also encouraged CMS to incorporate HEART into the CMS Data Element Library (DEL).

Response: We appreciate the commenters' suggestions on cross-setting issues. We 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 used in other quality reporting programs for different patient populations. 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. At the same time, we also agree that HEART is an opportunity to coordinate and harmonize with measure and data elements from other care settings, where applicable. Although hospice was not a care setting included in the IMPACT Act, we are coordinating within CMS to ensure HEART promotes continuity of care across the post-acute care continuum where feasible and appropriate.

9. Previously Adopted APU Determination and Compliance Criteria for the HQRP

a. Background

The HQRP is currently designed as a ''pay-for-reporting'' system, meaning that it is the act of submitting data that determines compliance with HQRP requirements. Performance level is not a consideration when determining market basket updates/APU. Reporting compliance is determined by successfully fulfilling both the Hospice CAHPS® Survey requirements and the HIS data submission requirements.

b. Previously Finalized HIS Data Submission Timelines and Compliance Thresholds for 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), we finalized the timeliness criteria for submission of HIS-Admission and HIS-Discharge records. The finalized timeliness criteria were 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.

As stated in that rule, 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 the timeliness criteria for submission of HIS-Admission and HIS-Discharge records, in the FY 2016 Hospice Wage Index final rule (80 FR 47192) we also finalized a policy 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 HIS-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 and thereafter, 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.

In July of 2016, we released the Hospice Timeliness Compliance Threshold Report in the Certification and Survey Provider Enhanced Reports (CASPER) system. This report allows providers with a QIES ASAP User ID to check their preliminary compliance with the 70/80/90 timeliness compliance threshold described above. For more information on the Hospice Timeliness Compliance Threshold Report, we refer readers to the Timeliness Compliance Threshold Fact Sheet, 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* and Chapter 3 of the CASPER User's Manual, available on the QTSO Web site: *https://www.qtso.com/hospicetrain.html*.

In the FY 2016 Hospice Wage Index final rule (80 FR 47192 through 47193), we 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), we also stated that 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 HIS Web page 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 CMS HQRP Web site, listserv messages via the Post-Acute Care QRP listserv, MLN Connects ® National Provider Calls & Events, MLN Connects ® Provider eNews and announcements on Open Door Forums and Special Open Door Forums.

c. CAHPS® Participation Requirements for FY 2018 APU Determination and Determinations for Subsequent 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 FY APU years (79 FR 50491).

In the FY 2017 Hospice Wage Index final rule, we finalized that to meet the HQRP requirements for the FY 2018, FY 2019 and FY 2020 APU payment determinations, 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 FY 2018 APU; 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 FY 2019 APU, and hospices would collect survey data on a monthly basis for the months of January 1, 2018 through December 31, 2018 for the full FY 2020 APU (81 FR 25529 through 25530). In the May 2017 proposed rule we proposed that in order to meet the HQRP requirements for the FY 2021 APU payment determination, hospices would collect survey data on a monthly basis for the months of January 1, 2019 through December 31, 2019 to qualify for the FY 2021 APU. In addition, we proposed that in order to meet the HQRP requirements for the FY 2022 APU payment determination, hospices would collect survey data on a monthly basis for the months of January 1, 2020 through December 31, 2020 to qualify for the FY 2022 APU.

10. HQRP Submission Exemption and Extension Requirements for the FY 2019 Payment Determination and Subsequent Years

a. Extraordinary Circumstances Exemption and Extension

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. Such extraordinary circumstances may include, but are not limited to, acts of nature or other systemic issues with our data systems. We further finalized that hospices must request such an exemption or extension within 30 days of the date that the extraordinary circumstances occurred. In certain instances, however, it may be difficult for hospices to timely evaluate the impact of extraordinary circumstances within 30 calendar days. For other quality reporting programs such as the Hospital Inpatient Quality Reporting (81 FR 57182), Inpatient Rehabilitation Facility Quality Reporting Program (81 FR 52125) and the Long term Care Hospital Quality Reporting Program (81 FR 25205), we have reevaluated our policy and subsequently finalized through rulemaking an extension of that period of time to 90 calendar days. Therefore, we proposed to extend the deadline for submitting an exemption or extension request to 90 calendar days from the qualifying event which is preventing a hospice from submitting their quality data for the HQRP. We believe that extending the deadline to 90 calendar days would allow hospices more time to determine whether it is necessary and appropriate to submit an exemption or extension request and to provide a more comprehensive account of the qualifying event in their request form to CMS. For example, if a hospice has suffered damage due to a hurricane on January 1st, it would have until March 31st to submit a request form to CMS via email to the HQRP mailbox at *HospiceQRPReconsiderations@cms.hhs.gov*.

Further, while we finalized our policy in the past for exception/extension for the submission of the HIS data, we proposed to extend this policy beyond the submission of the HIS date to submission of the CAHPS® Hospice Survey data, given that multiple data submission processes could be impacted by the same qualifying event. Therefore, we proposed for FY 2019 payment determination and subsequent payment determinations to extend the period of time a hospice may have to submit a request for an extension or exception for quality reporting purposes from 30 calendar days to 90 calendar days after the date that the extraordinary circumstances occurred, by submitting a request to CMS via email to the HQRP mailbox at *HospiceQRPReconsiderations@cms.hhs.gov*. Exemption or extension requests sent to us 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 HIS and/or CAHPS® Hospice Survey 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 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 the various means, including the CMS HQRP Web site, listserv messages via the Post-Acute Care QRP listserv, MLN Connects® National Provider Calls & Events, MLN Connects® Provider eNews and announcements on Open Door Forums and Special Open Door Forums.

We solicited comments on these proposals. The comments and our responses are set forth below.

Comment: Commenters were unanimously supportive of CMS's proposal to extend the deadline for submitting an exemption or extension request to 90 calendar days from the qualifying event which is preventing a hospice from submitting their quality data for the HQRP. One commenter believed the change in policy will enable hospice agencies to have more time to determine whether an emergency may warrant an extension or exemption request. Another commenter believed the change in policy will enhance fairness where acts of nature or a systemic problem on part of CMS's data collection system prevents compliance. One commenter requested clarification about form for submitting requests for exemption and extensions; specifically, what the appropriate mode of submission of exemption and extension requests is.

Response: We appreciate the commenters' support for the proposal to extend the submission deadline from 30 to 90 days. We agree that the change will be helpful for providers and maximize compliance and participation in the HQRP. Regarding the commenter's request for clarification on our policies for exemption and extension, including mode of submission of these requests, as noted in this rule, we accept requests for exemption and extension via email to the HQRP Reconsiderations mailbox at *HospiceQRPReconsiderations@cms.hhs.gov*. Procedures for exemptions and extensions are further outlined on the CMS HQRP Web site here: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Hospice-Quality-Reporting/Extensions-and-Exemption-Requests.html*.

Final Action: We are finalizing our proposal to implement the change in deadline from 30 to 90 days for hospices requesting an exemption or extension for the FY 2019 payment determination and subsequent payment determinations.

b. Volume-Based Exemption for CAHPS® Hospice Survey Data Collection and Reporting Requirements

We previously finalized a volume-based exemption for CAHPS® Hospice Survey Data Collection and Reporting requirements in the FY 2017 Final Rule (81 FR 52143). Hospices that have fewer than 50 survey eligible decedents/caregivers in the period from January 1, 2017 through December 31, 2017 are eligible to apply for an exemption from CAHPS® Hospice Survey data collection and reporting requirements for the FY 2020 payment determination (corresponds to the CY 2018 data collection period). To qualify, hospices must submit an exemption request form for the FY 2020 APU. The exemption request form is available on the official CAHPS® Hospice Survey Web site *http://www.hospiceCAHPSsurvey.org*. Hospices that intend 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 December 31, 2018. Small hospices that meet the exemption for size criteria for FY 2020 must complete an exemption form for FY 2020. Exemptions for size are active for 1 year only. If a hospice continues to meet the eligibility requirements for this exemption in future FY APU periods, the organization needs to request the exemption annually for every applicable FY APU period.

Hospices that have fewer than 50 survey eligible decedents/caregivers in the period from January 1, 2018 through December 31, 2018 are eligible to apply for an exemption from CAHPS® Hospice Survey data collection and reporting requirements for the FY 2021 payment determination. Hospices that intend to claim the size exemption are required to submit to CMS their total unique patient count for the period of January 1, 2018 through December 31, 2018. The due date for submitting the exemption request form for the FY 2021 APU is December 31, 2019. Small hospices that meet the exemption for size criteria for FY 2021 must complete an exemption form for FY 2021.

Hospices that have fewer than 50 survey eligible decedents/caregivers in the period from January 1, 2019 through December 31, 2019 are eligible to apply for an exemption from CAHPS® Hospice Survey data collection and reporting requirements for the FY 2022 payment determination. Hospices that intend to claim the size exemption are required to submit to CMS their total unique patient count for the period of January 1, 2019 through December 31, 2019. The due date for submitting the exemption request form for the FY 2022 APU is December 31, 2020. If a hospice continues to meet the eligibility requirements for this exemption in future FY APU periods, the organization should request the exemption annually for every applicable FY APU period.

c. Newness Exemption for CAHPS® Hospice Survey Data Collection and Reporting Requirements

We previously finalized a one-time newness exemption for hospices that meet the criteria (81 FR 52181). Accordingly, hospices that are notified about their Medicare CCN after January 1, 2018 are exempted from the FY 2020 APU CAHPS® Hospice Survey requirements due to newness. No action is required on the part of the hospice to receive this exemption. The newness exemption is a one-time exemption from the survey. Likewise, hospices notified about their Medicare CCN after January 1, 2019, are exempted from the FY 2021 APU CAHPS® Hospice Survey and hospices notified about their Medicare CCN after January 1, 2020, are exempted from the FY 2022 APU CAHPS® Hospice Survey requirements.

11. CAHPS® Hospice Survey Participation Requirements for the FY 2020 APU and Subsequent Years

The CAHPS® Hospice Survey of CMS' Hospice Quality Reporting Program is used to collect data on the experiences of hospice patients and the primary caregivers listed in their hospice records. Readers who want more information are referred to our extensive discussion of the Hospice Experience of Care prior to our proposal for the public reporting of measures should refer to 79 FR 50452 and 78 FR 48261.

a. Background and Description of the CAHPS® Hospice Survey

The CAHPS® Hospice Survey is the first standardized national survey available to collect information on patients' and informal caregivers' experience of hospice care. Patient-centered experience measures are a key component of the CMS Quality Strategy, emphasizing patient-centered care by rating experience as a means to empower patients and their caregivers and improving the quality of their care.[46] In addition, the survey introduces standard survey administration protocols that allow for fair comparisons across hospices.

Details regarding CAHPS® Hospice Survey national implementation, survey administration, participation requirements, exemptions from the survey's requirements, hospice patient and caregiver eligibility criteria, fielding schedules, sampling requirements, survey instruments, and the languages that are available for the survey, are all available on the official CAHPS® Hospice Survey Web site, *www.HospiceCAHPSsurvey.org* and in the CAHPS® Hospice Survey Quality Assurance Guidelines (QAG), which is posted on the Web site.

b. Overview of Proposed Measures

The CAHPS® Hospice Survey was developed in line with the U.S. Department of Health and Human Services' Transparency Initiative to measure patient experience. Unlike the Hospital CAHPS® Survey deployed in 2006 (71 FR 48037 through 48039) and other subsequent CAHPS® surveys, the CAHPS® Hospice Survey is administered after the patient is deceased and queries the decedent's primary caregiver regarding the patient and family experience of care. National implementation of the CAHPS® Hospice Survey commenced January 1, 2015 as stated in the FY 2015 Hospice Wage Index and Payment Rate Update final rule (79 FR 50452).

The survey consists of 47 questions and is available (using the mailed version) in English, Spanish, Chinese, Russian, Portuguese, Vietnamese, Polish, and Korean. It covers topics such as access to care, communications, getting help for symptoms, and interactions with hospice staff. The survey also contains two global rating questions and asks for self-reported demographic information (race/ethnicity, educational attainment level, languages spoken at home, among others). The CAHPS® Hospice Survey measures received NQF endorsement on October 26th, 2016 (NQF number 2651). Measures derived from the CAHPS® Hospice Survey include six multi-item (composite) measures and two global ratings measures under NQF 2651. We proposed to adopt these eight survey-based measures for the CY 2018 data collection period and for subsequent years. We believe these survey-based measures will be useful in assessing aspects of hospice care where the family/primary caregiver is the most useful or only source of information, and to allow meaningful and objective comparisons between hospice providers. The six CAHPS® Hospice Survey composite survey-based measures are:

- Hospice Team Communication;
- Getting Timely Care;
- Treating Family Member with Respect;
- Getting Emotional and Religious Support;
- Getting Help for Symptoms; and
- Getting Hospice Care Training.

Each of the six composite survey-based measures consists of two or more questions. The two global survey-based measures are:

- Rating of Hospice; and
- Willingness to Recommend Hospice.

The two global survey-based measures comprise a single question each and ask the primary caregiver of the decedent to rate the care provided by the hospice facility and his or her willingness to recommend the hospice to family and friends. More information about these measures can be found on the official CAHPS® Hospice Survey Web site, *www.HospiceCAHPSsurvey.org* and in

[46] CMS National Quality Strategy 2016. Available at: *https://www.cms.gov/medicare/quality-initiatives-patient-assessment-instruments/qualityinitiativesgeninfo/downloads/cms-quality-strategy.pdf.*

the CAHPS® Hospice Survey Quality Assurance Guidelines (QAG), which is posted on the Web site.

The eight survey-based measures we proposed were included on the CY 2016 MUC [47] list, and reviewed by the MAP.[48] They are as follows:

- CAHPS® Hospice Survey: Rating of Hospice (MUC ID: MUC16–31).
- CAHPS® Hospice Survey: Hospice Team Communications (MUC16–32).
- CAHPS® Hospice Survey: Willingness to Recommend (MUC16–33).
- CAHPS® Hospice Survey: Getting Hospice Care Training (MUC16–35).
- CAHPS® Hospice Survey: Getting Timely Care (MUC16–36).
- CAHPS® Hospice Survey: Getting Emotional and Religious Support (MUC16–37).
- CAHPS® Hospice Survey: Getting Help for Symptoms (MUC16–39)
- CAHPS® Hospice Survey: Treating Family Member with Respect (MUC16–40)

The MAP supported rulemaking for all eight ''patient-reported'' measures derived from the CAHPS® Hospice Survey. We received no comments about these items and therefore, we are adopting these measures as final for CY 2018.

c. Data Sources

As discussed in the CAHPS® Hospice Survey Quality Assurance Guidelines V3.0 (QAG V3.0) (*http://www.hospicecahpssurvey.org/en/quality-assurance-guidelines/*), the survey has three administration methods: Mail-only, telephone only, and mixed mode (mail with telephone follow-up of non-respondents). We previously finalized the participation requirements for the FY 2018 and FY 2019 Annual Payment Updates (80 FR 47194). To summarize, to meet the CAHPS® Hospice Survey requirements for the HQRP, we proposed that hospice facilities must contract with a CMS-approved vendor to collect survey data for eligible patients on a monthly basis and report that data to CMS on the hospice's behalf by the quarterly deadlines established for each data collection period. The list of approved vendors is available at: *http://www.hospicecahpssurvey.org/en/approved-vendor-list.*

Hospices are required to provide lists of the patients who died under their care, along with the associated primary caregiver information, to their respective survey vendors to form the samples for the CAHPS® Hospice Survey. We emphasize the importance of hospices providing complete and accurate information to their respective survey vendors in a timely manner. Hospices must contract with an approved CAHPS® Hospice Survey vendor to conduct the survey on their behalf. Hospices are responsible for making sure their respective survey vendors meet all data submission deadlines. Vendor failures to submit data on time are the responsibility of the hospices.

i. Requirements for the FY 2020 Annual Payment Update

To meet participation requirements for the FY 2020 annual payment update (APU), Medicare-certified hospices must collect CAHPS® Hospice Survey data on an ongoing monthly basis from January 2018 through December 2018 (all 12 months) in order to receive their full payment for the FY 2020 APU. All data submission deadlines for the FY 2020 APU are in Table 17. CAHPS® Hospice Survey vendors must submit data by the deadlines listed in Table 17 for all APU periods listed in the table and moving forward. There are no late submissions permitted after the deadlines, except for extraordinary circumstances beyond the control of the provider as discussed above.

TABLE 17—CAHPS® HOSPICE SURVEY DATA SUBMISSION DATES FOR THE APU IN FY 2020, FY 2021, AND FY 2022

Sample months (that is, month of death [1])	Quarterly data submission deadlines [2]
FY 2020 APU	
January–March 2018 (Q1)	August 8, 2018.
April–June 2018 (Q2)	November 14, 2018.
July–September 2018 (Q3)	February 13, 2019.
October–December 2018 (Q4)	May 8, 2019.
FY 2021 APU	
January–March 2019 (Q1)	August 14, 2019.
April–June 2019 (Q2)	November 13, 2019.
July–September 2019 (Q3)	February 12, 2020.
October–December 2019 (Q4)	May 13, 2020.
FY 2022 APU	
January–March 2020 (Q1)	August 12, 2020.
April–June 2020 (Q2)	November 12, 2020 [3].
July–September 2020 (Q3)	February 10, 2021.
October–December 2020 (Q4)	May 12, 2021.

[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 the months August, November, February, and May.
[3] Second Wednesday is Veterans Day Holiday.

ii. Requirements for the FY 2021 Annual Payment Update

To meet participation requirements for the FY 2021 APU, Medicare-certified hospices must collect CAHPS® Hospice Survey data on an ongoing monthly basis from January 2019 through December 2019 (all 12 months) in order to receive their full payment for the FY 2021 APU. All data submission deadlines for the FY 2021 APU are in Table 17. CAHPS® Hospice Survey vendors must submit data by the deadlines listed in Table 17 for all APU periods listed in the table and moving

[47] CMS, *List of Measures Under Consideration for December 1, 2016. Available at: https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityMeasures/Downloads/Measures-under-Consideration-List-for-2016.pdf.*

[48] The National Quality Forum. *MAP 2016–2017 Preliminary Recommendations.* National Quality Forum, 2016 Recommendations for Measures Under Consideration, Jan. 2017. *Available at: http://www.qualityforum.org/map/.*

forward. There are no late submissions permitted after the deadlines, except for extraordinary circumstances beyond the control of the provider as discussed above.

iii. Requirements for the FY 2022 Annual Payment Update

To meet participation requirements for the FY 2022 APU, Medicare-certified hospices must collect CAHPS® Hospice Survey data on an ongoing monthly basis from January 2020 through December 2020 (all 12 months) in order to receive their full payment for the FY 2022 APU. All data submission deadlines for the FY 2022 APU are in Table 17. CAHPS® Hospice Survey vendors must submit data by the deadlines listed in Table 17 for all APU periods listed in the table and moving forward. There are no late submissions permitted after the deadlines, except for extraordinary circumstances beyond the control of the provider as discussed above.

d. Measure Calculations

As noted above, we proposed to adopt six composite CAHPS® Hospice Survey-based measures and two global survey-based measures. As with other measures adopted for HQRP, a hospice's performance for a given payment determination year will be based upon the successful submission of data required in accordance with the administrative, form, manner and timing requirements established for the program. Therefore, hospices' substantive scores on the CAHPS® Hospice Survey-based measures will not affect whether they are subject to the 2.0 percentage point payment reduction for hospices that fail to report data required to be submitted. Rather, the 2.0 percentage point reduction will be applied based on whether the data were submitted in accordance with our requirements.

We proposed that CAHPS® Hospice Survey scores for a given hospice be displayed as ''top box'' scores, with the national average top-box score for participating hospices provided for comparison. Top-box scores reflect the proportion of caregiver respondents that endorse the most positive response(s) to a given measure, such as the proportion that rate the hospice a 9 or 10 out of 10 on a 0 to 10 scale, or the proportion that report that they ''always'' received timely care. The top-box numerator for each question within a measure is the number of respondents that endorse the most positive response(s) to the question. The denominator includes all respondents eligible to respond to the question, with one exception. The exception is the Getting Hospice Care Training measure; for this measure, the measure score is calculated only among those respondents who indicated that their family member received hospice care at home or in an assisted living facility.

For additional information on the specifications of these measures, including details regarding top-box scoring methodology and mode and case-mix adjustment, please refer to the CAHPS® Hospice Survey Web page at *http://www.hospicecahpssurvey.org/en/*.

i. Composite Survey-Based Measures

Unadjusted hospice scores on each composite CAHPS® Hospice Survey-based measure would be calculated by determining the proportion of ''top-box'' responses for each question within the composite and averaging these proportions over all the questions in the composite measure. For example, to assess hospice performance on the composite measure CAHPS® Hospice Survey—Hospice Team Communication, we would calculate the proportion of top-box responses for each of the measure's six questions, add those proportions together, and divide by the number of questions in the composite measure (in this case, six).

As a specific example, we take a theoretical hospice facility that had 50 surveys completed and received the proportions of ''top-box'' responses through sample calculations:

- 25 ''top-box'' responses out of 50 total responses on Question One
- 40 ''top-box'' responses out of 50 total responses on Question Two
- 50 ''top-box'' responses out of 50 total responses on Question Three
- 35 ''top-box'' responses out of 50 total responses on Question Four
- 45 ''top-box'' responses out of 50 total responses on Question Five
- 40 ''top-box'' responses out of 50 total responses on Question Six

Based on the above responses, we would calculate that hospice's unadjusted measure score for public reporting as follows:

Publicly Reported Score. = ((0.5 + 0.8 + 1 + 0.7 + 0.9 + 0.8))/6)

This calculation would give this example hospice an unadjusted score of 0.78 or 78 percent for the Hospice Team Communication measure for purposes of public reporting. We note that an adjusted hospice score would be calculated by adjusting the score for each question for differences in the characteristics of decedents and caregivers across hospices and for mode, and then averaging across questions within the measure as described here. Further detailed information regarding scoring and risk adjustment can be found at the CAHPS® Hospice Survey Web site (*http://www.hospicecahpssurvey.org/en/technical-specifications/*).

ii. Global Survey-Based Measures

We proposed to adopt two global CAHPS® Hospice Survey measures. CAHPS® Hospice Survey—Rating of Hospice asks the primary caregiver of the decedent to rate the care provided by the hospice on a scale of 0 to 10, and CAHPS® Hospice Survey—Willingness to Recommend asks about the caregiver's willingness to recommend the hospice to family and friends on a scale of ''Definitely No'' to ''Definitely Yes''. Unadjusted hospice performance on each of the two global CAHPS® Hospice Survey-based measures would be calculated by the proportion of respondents providing high-value responses (that is, a 9 to 10 rating or ''Definitely Yes'') to the survey questions over the total number of respondents. For example, if a hospice received 45 ratings of 9 or 10 points out of 50 responses, this hospital would receive a 0.9 or 90 percent unadjusted score, which would then be adjusted for differences in the characteristics of decedents and caregivers across hospices and modes.

iii. Cohort

The CAHPS® Hospice Survey is administered to all eligible patients/caregivers—or a random sample thereof—who meet the eligibility criteria. Eligible patients, regardless of insurance or payment, can participate.

For purposes of each survey-based measure captured in the CAHPS® Hospice Survey, an ''eligible patient'' is a decedent 18 years or older:

- With death at least 48 hours following last admission to hospice care.
- for whom there is a caregiver of record.
- whose caregiver is someone other than a non-familial legal guardian.
- for whom the caregiver has a United States or United States Territory home address.

Patients who are still alive or whose admission to the hospice resulted in a live discharge, are not eligible to participate in the survey. In addition, decedents/caregivers who initiate or voluntarily request that the hospice not reveal the patient's identity; and/or not survey the patient/caregiver (''no publicity patients/caregivers'') are excluded from the sample.

e. Risk Adjustment

The CAHPS® Hospice Survey measures assess activities that are fully under the control of hospice care professionals and/or hospice organizations. In order to ensure fair comparisons in public reporting, we believe it is necessary and appropriate to adjust for factors that are not directly related to hospice performance, such as patient mix, for these CAHPS® Hospice Survey measures. The survey based measures are adjusted for decedent and caregiver characteristics (including the lag time between patient death and survey response; decedent's age, payer for hospice care, decedent's primary diagnosis, decedent's length of final episode of hospice care, caregiver's education, decedent's relationship to caregiver, caregiver's preferred language and language in which the survey was completed, and caregiver's age) known to be associated with systematic difference in survey responses.

i. Patient-Mix Adjustment

Previous research, on both CAHPS® surveys and other types of surveys, has identified respondent characteristics that are not under the control of the entities being assessed but tend to be related to survey responses. Hence, variations in the proportion of respondents with such characteristics will be associated with variations in survey responses that are unrelated to the actual quality of hospice care. To ensure that comparisons between hospices reflect differences in performance rather than differences in patient and/or caregiver characteristics, publicly reported hospice scores will be adjusted for variations of such characteristics across hospices. This adjustment is performed using a linear regression model applied to all data within a quarter, with indicator variables for each hospice and each characteristic as an independent variable in the model.

ii. Mode Adjustment

We conducted an experiment to determine whether survey mode adjustments were needed to fairly compare CAHPS® Hospice Survey scores. The experiment found that mode adjustments are needed. Publicly reported CAHPS® Hospice Survey scores will be adjusted for the mode of survey administration, which affects scores but is not related to quality of hospice care (Authorized survey modes are: mail-only, telephone-only, and mail with telephone follow up, also called mixed mode.). Mode adjustment is performed prior to patient-mix adjustment; a mode adjustment value is added/subtracted (depending on the mode) to each response to the survey by mail-only mode or mixed mode. Responses obtained using telephone-only mode are not adjusted since this is the reference mode. As a result of the risk adjustment methodologies proposed here, the final percentages may vary from the unadjusted percentage as calculated in the examples provided above.

f. For Further Information About the CAHPS® Hospice Survey

We encourage hospices and other entities to learn more about the survey on *www.hospicecahpssurvey.org*. For direct questions, please contact the CAHPS® Hospice Survey Team at *hospicecahpssurvey@HCQIS.org* or telephone 1–844–472–4621.

The comments and our responses are set forth below.

Comment: One commenter stated that: ''typically anything that is impacted significantly by patient perception—subjective measures regarding quality of an end of life process are probably not going to be meaningful. Combined with low health literacy surrounding dying/end of life and then tying these measures to the hospice payment structure is probably damaging. Patients and their families probably receive all of their knowledge about the dying process from hospices themselves, and since that topic is quite deep to begin with, and the emotional state of many families and patients is not one that is prepared to learn in their circumstances, their responses to their surroundings/the proceedings of hospice probably do not reflect the actual care they are receiving.''

Response: We believe that patient experience surveys constitute a useful element in quality reporting programs. Our Hospice CAHPS® survey was designed using interviews with caregivers, providers and other interested professionals to include questions that address the domains of interest to the caregiving public. Survey results, combined with other measures such as the HIS, can provide a more rounded view of hospice quality. Hospices can, and we believe do, use CAHPS® results to help them with quality improvement.

Comment: Several commenters expressed reservations about the timeframe for reporting CAHPS® Hospice Survey results publicly on Hospice Compare. Commenters thought the data would be too outdated and that it would not reflect adjustments and quality improvement efforts by the hospices.

Response: We are currently planning on reporting scores using a rolling average over the most recent eight quarters. We are trying to balance two competing goals. First, we want to present reliable data. Second, we want to include as large a proportion of hospices as possible on the Hospice Compare site. Small sample sizes tend to be less reliable than larger ones. This means that displaying data for hospices with only a few completed surveys results in providing less reliable data. On the other hand, if we only report results with large numbers of completes, a great many hospices will not appear on the Compare site at all. We tried to avoid both problems by elongating the amount of time we are using to report the data. We hoped this would produce larger numbers of completed surveys for the smaller hospices, thus allowing them to be reported with more reliable data. We are willing to consider other options and would welcome more input from hospices.

Comment: One commenter suggested that CMS look at ways to ameliorate the age of the publicly reported data by ''appropriately weighting the current data and separately weight the older data or not include it at all. Further exploration is needed to include patient/respondent characteristics that may have an impact on the CAHPS® survey responses, including issues that are not currently specified for use in the risk adjustment of CAHPS® responses.''

Response: We will explore options, if any, offered by weighting schemes for the publicly reported data. We assume the commenter would want the newest data weighted more heavily than older data. We are also willing to continue to examine patient and respondent characteristics that may be suitable for case mix adjustment. Remember that case mix variables must be variables that are beyond the control of the hospice.

Comment: Another commenter suggested that CMS consider using a six month analysis with the most current data for the reporting of CAHPS® results. The commenter was concerned that the eight-quarter rolling reporting period for CAHPS® results could be misleading to the public as organization improvement would not be seen for an extended period and not reflect current performance.

Response: We will continue to review the decision to use an eight-quarter average. We are aware that there are several potential pitfalls with survey data. One of the characteristics of small samples is that the results may shift greatly month to month because of one or a few outliers among respondents. As

a result, including small hospices with small samples sizes on the Compare site also creates the risk of misleading the public. On the other hand, we are reluctant to restrict the Hospice Compare site to large hospices. We welcome more input from hospices on this issue.

Comment: One commenter suggested that CMS consider displaying two sets of data on Hospice Compare, one for eight quarters of data and one for four quarters of data, which would address concerns about the age of the data.

Response: We thank the commenter for this suggestion. We are aware of the concerns about the age of the data. We believe displaying two sets of CAHPS® data would make the CAHPS® pages on Hospice Compare more complex and might confuse members of the public.

Comment: One commenter stated that analysis of missing data for the CAHPS® Hospice Survey is needed to determine how well the survey results represent the totality of hospice care quality and assist hospices with the interpretation of survey results for quality improvement programs.

Response: Our analysis of CAHPS® Hospice Survey data suggest that adjustment for differences in case mix, as is done when calculating CAHPS® Hospice Survey measure scores, adequately addresses nonresponse bias associated with these case mix characteristics.

Comment: CMS should conduct ongoing analysis of the demographics and other characteristics (for example, age, gender, diagnosis, geographic area, care setting, etc.) for those patients whose caregivers (a) are not included in Hospice CAHPS® administration; or (b) do not complete a survey. This information at a minimum should be shared with hospice providers so it can be used to inform their quality improvement efforts and development of strategies to improve survey response rates. CMS should also consider including these results in Hospice Compare to provide consumers with an idea of the degree that Hospice CAHPS® survey respondents may differ from themselves.

Response: We are conducting ongoing analyses of the characteristics of decedents for whom CAHPS® Hospice Surveys are completed, and is considering a variety of means for sharing this information with hospices.

Comment: One commenter said that caregiver involvement in care should be included in case mix adjustment of the CAHPS® Hospice Survey measures.

Response: Case-mix adjustment addresses factors that are systematically associated with differences in how caregivers respond to the CAHPS® Hospice Survey, and that are not in the control of the hospice. Hospice activities may influence the degree of caregiver involvement.

Comment: One commenter noted that the 47 CAHPS® hospice survey questions do not address the care planning and/or patient and family/family caregiver shared decision making. The commenter also noted that the CAHPS® survey does ask related questions, but only after the death of the patient.

Response: We chose to make Hospice CAHPS® a survey of caregivers that occurs after the death of the patient, in order to obtain information about the entire trajectory of hospice care, not just the care upon which the patient was themselves able to respond. As the commenter noted, the survey does ask questions related to care planning and shared-decision making. When developing the questions for the survey we focused on domains that caregivers told us were important to them. We are willing to consider other questions for inclusion in the survey and will think further about care planning and shared decision making in the future.

Comment: One commenter mentioned that there are no questions about the ''extent to which the family was able to satisfactorily or confidently engage in the care or support of their terminally ill family member.''

Response: We are willing to consider items for inclusion in the survey. We think the subject raised by the comment would be related to how often hospice training resulted in the caregiver being confident in caring for or support of a terminally ill patient.

Comment: One commenter supported ''that CAHPS® Hospice Survey scores for a given hospice be displayed as ''top-box'' scores, with the national average top-box score for participating hospices provided for comparison. This will allow hospice providers to understand their measures and identify areas for improvement.''

Response: We are planning to include national average top box scores for CAHPS® on Hospice Compare.

Comment: One commenter suggested that CMS incorporate additional information into the Hospice Compare Web site. Specifically, they recommended helping the users understand what the hospice benefit entails. They also suggested that the site provide advice on how to use quality reports to choose hospices.

Response: We are designing the Hospice Compare site to provide users with information about the hospice benefit. We are also testing the site to make sure it is understandable to the public. We will provide information about how the data are calculated and what it includes when the hospice data is published on Hospice Compare. We anticipate this occurring in the Winter of 2018.

Comment: One commenter said, ''It would be wonderful if there were comments and explanations that tell the story of what the HIS and data elements were saying. A summary of sorts?''

Response: We appreciate the commenter's suggestion and will consider for the future, including a guide or legend that describes the measures. We agree that stakeholders would find this useful.

Comment: One commenter raised a concern about some of the national benchmarking scores for CAHPS®, asking if it is a valid measure when the national benchmark scores are all low in one area. The commenter also asked if anyone is evaluating these survey items.

Response: We are not certain what the commenter means by ''benchmark scores are all low in one area.'' It is unclear if the commenter means a geographic area or a topic area. Hospice usage and quality can and does vary by geographic region. The questions included in the Hospice CAHPS® survey are thoroughly reviewed by the Agency for Healthcare Research and Quality (AHRQ) and other healthcare and research professionals. The CAHPS Hospice Survey was awarded use of the CAHPS trademark after extensive review by AHRQ's CAHPS® Consortium. Measures from the survey were reviewed and endorsed by the National Quality Forum (NQF #2651). The questions were also reviewed by the multi-stakeholder MAP, which guides the selection of measures for HHS.

Comment: One commenter raised the issue of fairness regarding hospices that are not included in Hospice Compare due to their small volume of patients served and their length of service.

Response: We are aware of the issue as it impacts inclusion in Hospice Compare. This is the major rationale for showing eight quarters of data—it allows us to display more reliable data for more hospices. We welcome further advice on how best to handle the fairness issue while at the same time providing accurate information to the public. We also welcome alternative suggestions for a solution to this issue.

Comment: One commenter noted, ''Families often tell hospice providers they do not understand why they were sent a second CAHPS® survey. They state that they either complete the second survey or assume we sent it by mistake. Many question the program's

organizational skills. The instructions/process sent with the surveys needs to be clearer for bereaved family members.''

Response: We will work with vendors to make sure that caregivers know why they received a second survey. Much of the time the reason is that the caregiver's completed survey is sent late enough that we are into a second wave of mailings to ''non-respondents.'' The questionnaires cross in the mail.

12. HQRP Reconsideration and Appeals Procedures for the FY 2018 Payment Determination and Subsequent Years

In the FY 2015 Hospice 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 HQRP 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: *https://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 (USPS) or phone will not be considered as a valid reconsideration request. In the FY 2017 final rule (81 FR 52143) we further clarified that providers should submit reconsideration requests of decision by CMS that the hospice has not met the CAHPS® Hospice Survey requirements using the same process (81 FR 52181). (Details about the reports and emails received after data submission are in the CAHPS® Hospice Quality Assurance Guidelines, which is available on the official CAHPS® Hospice Survey Web site, *www.hospicecahpssurvey.org*). 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 of this final rule. 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/2017-Transmittals.html*.

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 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 have implemented this additional communication mechanism via the CASPER Hospice Timeliness Compliance Threshold Report previously discussed in the FY 2017 Hospice Wage Index proposed rule at 81 FR 25527 and 25528. We will continue to send notification of noncompliance via delivery of a letter via the USPS. We previously finalized our proposal (80 FR 47198) to publish a list of hospices who successfully meet the reporting requirements for the applicable payment determination on the CMS HQRP Web site. The list of providers found to be compliant with the FY 2017 APU requirements can be found on the CMS HQRP Web site here: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Hospice-Quality-Reporting/HQRP-Requirements-and-Best-Practices.html*.

13. Confidential Feedback Reports

As part of our effort to promote use of standardized quality data to improve quality of care, in December 2016, we made available two new provider feedback reports: The Hospice-Level Quality Measure Report and the Patient Stay-Level Quality Measure Report. These confidential feedback reports are available to each hospice using the CASPER system, and are part of the class of CASPER reports known as Quality Measure (QM) Reports. These reports are separate from public reporting and are for provider viewing only (to the extent permissible under federal law), for the purposes of internal provider quality improvement. These reports are on-demand and thus enable hospice providers to view and compare their performance to the national average for a reporting period of their choice.

Hospices are able to view their data and information at both the hospice and patient stay levels for their HIS-based quality measures. The CASPER hospice-level QM Reports contain information such as the numerator, denominator, hospice-level QM score, and national average. The CASPER patient stay-level QM Reports show whether each patient stay is counted toward each quality measure. The HIS based QMs reported in both reports include:

- NQF #1641 Treatment Preferences
- NQF #1647 Beliefs/Values
- NQF #1634 Pain Screening
- NQF #1637 Pain Assessment
- NQF #1639 Dyspnea Screening
- NQF #1638 Dyspnea Treatment
- NQF #1617 Bowel Regimen

For more information on the CASPER QM Reports, we refer readers to the CASPER QM Factsheet on the HQRP Web site at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Hospice-Quality-Reporting/HQRP-Requirements-and-Best-Practices.html*. This fact sheet contains detailed information about each CASPER QM report currently available, the data included in the reports, and how providers can use the reports as part of their Quality Assessment and Performance Improvement (QAPI) efforts. For technical information on the reports and how to access the CASPER QM Reports, we refer readers to: *https://www.qtso.com/hospicetrain.html*.

As new HIS measures are implemented in the HQRP, we will continue to expand the functionality of the QM reports to allow providers to view data on additional HIS measures. We will announce refinements and additions to the QM reports through sub-regulatory communication channels and in future rulemaking cycles.

We also proposed to provide hospices with preview reports of their data prior to the quarterly publication of CAHPS® Hospice Survey data on the Compare site. The reports will be provided through the CASPER reporting system. Each hospice will receive only its own, individual reports.

14. 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. These procedures shall ensure that a hospice has the opportunity to review the data that is to be made public for the hospice prior to such data being made public. The Secretary shall report quality measures that relate to hospice

care provided by hospice programs on a publicly available CMS Web site.

In the FY 2017 Hospice final rule, we discussed our analysis of HIS data to inform which measures were eligible for public reporting and reportability analysis to determine data selection period and minimum denominator size for measures to be publicly reported. Based on analysis results, we determined that all 7 HIS quality measures adopted for the FY 2016 and beyond (NQF #1634, NQF #1637, NQF #1639, NQF #1638, NQF #1641, NQF #1647, NQF #1617), calculated based on a rolling 12-month data selection period, to be eligible for public reporting with a minimum denominator size of 20 patient stays. For additional details on these analyses, we refer readers to the FY 2017 Hospice final rule (81 FR 52183 through 52184).

In the FY 2017 Hospice final rule, we also clarified policies for reportability analyses for new measures. As stated in the FY 2017 Hospice final rule, new measures will undergo reportability analysis to determine (1) appropriateness for public reporting and (2) appropriate data selection period. In accordance with discussion in the prior year's rule, we will use the same analytic approach used in previous reportability analyses to determine data selection period and minimum denominator size for the Hospice and Palliative Care Composite Process Measure—Comprehensive Assessment at Admission. We will begin reportability analyses for the Hospice Visits When Death is Imminent Measure Pair once data for the measure are available. Results of reportability analyses conducted for these new measures will be communicated through future rulemaking.

To meet the Affordable Care Act's requirement for making quality measure data public, we are developing a CMS Hospice Compare Web site, which will allow consumers, providers and stakeholders to search for all Medicare-certified hospice providers and view their information and quality measure scores. We anticipate that public reporting of HQRP data on the CMS Compare Web site will begin August 2017. To help providers prepare for public reporting, we will offer opportunities for stakeholder engagement and education prior to the rollout of a CMS Hospice Compare site. We will offer outreach opportunities for providers through CMS HQRP Public reporting Web page: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Hospice-Quality-Reporting/Hospice-Quality-Public-Reporting.html*, listserv messages via the Post-Acute Care QRP listserv, MLN Connects® National Provider Calls & Events, MLN Connects® Provider eNews and announcements on Open Door Forums and Special Open Door Forums. Finally, we will offer educational support and outreach to all hospice providers on the systems and processes for reviewing their data prior to public reporting; availability of educational support and outreach opportunities will be communicated through the listed channels above.

We will provide hospices an opportunity to preview their quality measure data prior to publicly reporting information. 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 preview their quality measure data prior to public reporting on the CMS Hospice Compare Web site. We will provide hospices 30 days to review the preview report beginning from the date on which they can access the report. Hospices will have an opportunity to request review of their data by CMS during the 30 day preview period if they believe that errors in data submitted to CMS may have resulted in incorrect measure scores and can submit proof along with a plan describing how the errors will be corrected. We will review these requests and if we confirm that the errors have affected the measures and agree to correct the measure, we will suppress the measure on the Hospice Compare Web site for one time only and display the corrected measure during the subsequent quarterly refresh of the Compare Web site. When the preview reports are ready for providers to access, anticipated August 2017 prior to the release of Hospice Compare, we will post the policies and procedures for providers to submit requests for reviewing of their data by CMS on the CMS HQRP Web site: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Hospice-Quality-Reporting/Hospice-Quality-Public-Reporting.html*. CMS encourages hospices to use CASPER QM Reports (see section III.D.14 of the FY 2018 proposed rule) to review their HIS quality measures after they submit the HIS data to CMS. If hospices determine that erroneous data have been submitted, they should submit either of these two types of HIS records: Modify existing record or inactivate existing record to correct their data. HIS data corrected before the data are frozen for the creation of the preview reports will be reflected in the preview reports.

We proposed to begin public reporting of CAHPS® Hospice Survey measures in 2018. Specifically, we proposed to publicly report data in winter CY 2018 on all eight CAHPS® Hospice Survey measures. Scores would be displayed based on eight rolling quarters of data and would initially use CAHPS® Hospice Survey data collected from caregivers of patients who died while receiving hospice care between April 1, 2015 and March 31, 2017. We proposed that the display of these scores be updated quarterly, and that scores be displayed only for those hospices for which there are 30 or more completed questionnaires during the reporting period. Scores will not be displayed for hospices with fewer than 30 completed questionnaires during the reporting period.

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 the CMS HQRP Web page, listserv messages via the Post-Acute Care QRP listserv, MLN Connects® National Provider Calls & Events, MLN Connects® Provider eNews 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, we have posted a hospice directory and quality data on a public data set located at *https://data.medicare.gov*. 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 have initially posted demographic data of hospice agencies that have been registered with Medicare. This list includes high-level demographic data for each agency, including provider name, address, phone numbers, ownership type, CCN, profit status, and date of original CMS certification. The posting of this hospice data directory

occurred on June 14, 2016, and will be refreshed quarterly. Information can be located at *https://data.medicare.gov/data/hospice-directory*. Additionally, we have posted two hospice data files containing national level aggregate quality data regarding seven HIS quality measures and CAHPS® Hospice Survey measures in December 2016. These data files are a one-time release with a goal to make quality data available prior to the release of the Hospice Compare in August 2017. Additional details regarding hospice datasets will be announced via the CMS HQRP Web page, listserv messages via the Post-Acute Care QRP listserv, MLN Connects® National Provider Calls & Events, MLN Connects® Provider eNews and announcements on Open Door Forums and Special Open Door Forums. In addition, we have provided the list of CASPER/ASPEN contacts, Regional Office and State coordinators in the event that a 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*. Once the Hospice Compare Web site is released in August 2017, *https://data.medicare.gov* will post the official datasets used on the Medicare.gov Compare Web sites provided by CM.

The comments and our responses are set forth below.

Comment: CMS received several comments that were supportive of public reporting of hospice quality measures. Commenters noted that they were in favor of CMS' efforts to publicly report hospice quality data to support the timely and transparent reporting of HQRP data to hospice beneficiaries, their families and caregivers, providers, and other stakeholders. One commenter shared that the public reporting of hospice quality data was essential to achieving industry goals of delivering the right care, to the right patient, at the right time. Several commenters had suggestions, recommendations, and concerns about specific aspects of the public display of HIS 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 the public display of quality measures in our responses below.

Comment: One commenter expressed concern that hospices not included in public reporting due to not meeting the minimum denominator size for public reporting, may be disadvantaged. This commenter believed that the lack of data on the Hospice Compare Web site may disadvantage these smaller providers as consumers may unfairly assume that the lack of publicly displayed data indicates lower quality providers. The commenter believed that this may raise an issue of fairness, whereby those hospices without publicly displayed quality data may be negatively impacted by consumers who misinterpret missing data as an indicator of quality in and of itself and choose not to receive services from these providers. To mitigate this issue, the commenter suggested that CMS develop a means to counterbalance the potential negative consequences for these hospices for which quality information is not publicly displayed.

Response: We appreciate the commenter sharing concerns regarding the possible negative impact of the minimum denominator size on small hospices. The minimum denominator size of 20 patient stays for HIS data was established through extensive data analysis to ensure that QM scores were statistically meaningful and reliable. The determination of the minimum denominator size balanced the necessity of yielding statistically meaningful QM scores and the goal of allowing as many hospices as possible to have their QM scores publicly displayed. Analysis conducted by RTI International shows that only about 10 percent of hospices would not have accumulated enough patient stays to have their HIS quality measures publicly displayed. The results of this data analysis are summarized in the Measure Testing Executive Summary document 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*. In order to counterbalance any potential negative impact of some hospices not having their measure data publicly displayed, we plan to clearly indicate on the Hospice Compare Web site instances where data is not displayed due to a small denominator size. We believe that this will signal to consumers that, in such instances, the lack of data is not an indication of poor quality but rather a result of the hospice having too few admissions to allow for reporting of a reliable QM. This approach is consistent with other quality reporting programs. We will also consider future education and outreach activities to educate consumers about the minimum denominator size for public reporting to inform the public that a lack of publicly displayed data does not necessarily indicate of poor quality.

Comment: One commenter noted that many providers have high scores on the current HIS-based QMs and that the limited range of scores could make it difficult for consumers to differentiate between high and low quality providers. The commenter suggested that publicly displayed data be presented as a rating or in another similar format.

Response: We agree that many hospice providers are performing well on the HIS-based QMs. The overall distribution and variability of the scores of the seven HIS QMs that will be publicly displayed initially indicate that most hospices are completing the important care processes for most hospice patients around hospice admission. However, there is still noticeable room for improvement. Analysis completed by RTI International shows that a low percentage of hospices have perfect scores for most measures and a small percentage of hospices have very low scores. To view the results of these analyses please see the Measure Testing Executive Summary document posted on the ''Current Measures'' portion of the CMS HQRP Web site at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Hospice-Quality-Reporting/Current-Measures.html*. In preparation for public reporting, CMS's measure development contractor, RTI International, interviewed hospice caregivers. Interviews with these caregivers found that public display of these measures would be useful in avoiding low-performing providers. Additionally, publicly reporting these measures inform consumers the important care processes that they should expect upon hospice admission.

Finally, the Hospice Compare Web site will likely feature a quality rating system that gives each hospice a rating such as between 1 and 5 stars. This will help supplement the measure scores by presenting the data as a rating. We will announce the timeline for the development and implementation of the star rating system in future rulemaking.

Comment: CMS received a few comments raising concerns about consumers' understanding of quality measure data reported on the Hospice Compare Web site. They recommended that CMS ensure that all information posted to the Web site is meaningful

and easily understandable to the general public. Commenters suggested that supplemental information, including general descriptions of the Medicare hospice benefit and consumer-friendly explanations of the HIS data be included on the Hospice Compare Web site to provide context for interpretation of publicly reported quality data. Furthermore, one commenter suggested CMS engage patients, caregivers, providers, and other stakeholders in the development process for the Hospice Compare Web site to ensure that the data presented are meaningful and actionable.

Response: We appreciate commenters' suggestions on information to include on the Hospice Compare Web site. We will take these into consideration as we continue to develop the Web site. We are committed to ensuring that all publicly reported data is presented in an appropriate and meaningful manner to the public. As such, we are working with our Web site development contractor to ensure that the Hospice Compare Web site will be tested for usability, readability, and navigation before its launch in August 2017. Consumers and stakeholders are continuously involved and are having opportunities for input throughout the development process. Text on the Hospice Compare Web site will comply with the Plain Writing Act of 2010. In addition to complying with the Plain Language Act, we are also taking into account variations in health and general literacy, and are soliciting input from key stakeholders and technical experts in the development and presentation of publicly available data.

Comment: A commenter raised concerns that public reporting of quality measures could lead to negative unintended consequences for hospice providers, such as reduced referrals.

Response: We appreciate the commenter's concerns about potential negative implications of public reporting of quality data. It is our hope that the public display of hospice-level data will provide an incentive to providers to identify areas of improvement and develop performance improvement plans to improve the quality of care delivered to their patients and their performance on quality measures. By developing performance improvement plans around areas for improvement, hospices can help minimize negative impacts on referrals. We will continue to carefully consider any potential unintended consequences of public reporting as we develop and report future HIS-based measures.

Comment: A few commenters expressed concerns that data reported in the inaugural release of the Hospice Compare Web site would be incorrect, and cited two main reasons for potential inaccuracies in data. One commenter believed that provider knowledge gaps about measure specifications could lead to errors in coding of HIS items and, subsequently, errors in measure scores and the display of incorrect measure data. The commenter encouraged CMS to identify knowledge gaps and quickly provide education to correct these misunderstandings so that inaccurate data (that is, data that is not reflective of actual care processes taking place but rather of inaccurate coding of HIS items) is not reported on Hospice Compare. A second reason that commenters provided was that there was insufficient time to preview HIS data submissions prior to public reporting. These commenters believed that hospices did not have sufficient time to correct data during the 30-day preview period.

Response: We appreciate commenters taking time to express their concerns about the accuracy of publicly reported data. We agree that it is of the upmost importance that data presented on the Web site is accurate and that providers have all the information and training necessary to accurately report HIS-based quality measure scores. We encourage providers to submit questions about measure specifications, coding guidance for HIS items, public reporting, and the preview period to the Hospice Quality Help Desk at *HospiceQualityQuestions@cms.hhs.gov*. We monitor common types of questions submitted to the Help Desk and use this information to determine potential knowledge gaps that should be the focus of regular outreach and education efforts. Such regular education efforts and clarifications in coding guidance for the HIS are communicated to providers on a regular basis through quarterly Question & Answer documents, Help Desk guidance, spotlights and announcements, and MLN eNews Listservs. We encourage providers to regularly check the CMS HQRP Web page for these educational materials. We routinely communicate updates about measure specifications and/or HIS items through these educational and communication outlets.

To prevent the public display of incorrect HIS measure data, we encourage hospices to use their CASPER QM reports (see section III.D.13 of the FY 2018 Hospice proposed rule) to regularly review their HIS quality measure scores. If hospices determine that erroneous data have been submitted, providers should use the HIS record modification and inactivation processes, as outlined in the HIS Manual available on the ''Hospice Item Set (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*. Hospice providers can submit modification and inactivation requests up to 36 months from the target date of any given HIS record. Regular monitoring of CASPER QM reports will help ensure that erroneous data are identified early and errors can be corrected in a timely manner. In addition to using QM reports as a mechanism for identifying errors, we also encourages hospices to proactively prevent errors in submitted data by ensuring that staff and clinicians are trained on the latest coding guidance, and that quality assurance and monitoring processes are in place to prevent the submission of incorrect data. We would like to note that HIS data corrected after the data are frozen for the creation of the Provider Preview Reports will not be reflected in the upcoming Hospice Compare Web site update, but will be displayed in the subsequent quarterly update. Because of this, we encourage providers to implement quality assurance and monitoring processes and check CASPER QM reports frequently.

Once the preview reports are generated, the underlying data cannot be corrected. If a hospice disagrees with the QM scores presented in their preview report, the hospice will have the opportunity to request review of their data by CMS during the 30-calendar day preview period. We will review these requests and if CMS agrees that the data is incorrect, the data will be suppressed for one quarter and the corrected data will be posted during the subsequent quarterly refresh of the Compare site. The process for CMS review of data is posted on the ''Hospice Quality Public Reporting'' portion of the CMS HQRP Web site: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Hospice-Quality-Reporting/Hospice-Quality-Public-Reporting.html*. The 30-calendar day preview period for Hospice Compare is consistent with preview periods in other quality reporting programs and has been sufficient in other settings. We encourage providers to sign up for the Post-Acute Care QRP listserv for more information about preview report roll-out and the preview period. We will take concerns about the length of the preview period into consideration for

future updates to public reporting of quality data.

Comment: CMS received several comments in support of the future development of a star rating system for the Hospice Compare Web site. Commenters provided several suggestions on creating a star rating system that would be useful to consumers and providers. A majority of commenters were opposed to a normative approach to calculating star ratings where ratings are placed on a bell curve. They believed that this approach would be confusing to consumers and not truly indicative of hospice performance. Commenters preferred a criterion approach for star ratings where CMS would establish benchmarks and calculate ratings based on hospice performance in relation to the established quality benchmark. Other commenters suggested that the star ratings include criteria beyond measure scores, such as patient/family satisfaction, financial performance, geographic indicators, and specialized services provided by the hospice.

Response: We appreciate commenters' detailed input on the development of a star rating methodology for hospice. While we have not set a date for implementing such a system, it is of paramount concern to us to develop a star rating methodology that is valid, reliable, and meaningful to consumers. We will alert our stakeholders once we are closer to entering that phase. We will provide continued opportunities for the provider community and other stakeholders to comment on and provide input to development of a star a proposed rating system. In addition to regular HQRP communication channels, we expect to solicit input from the public regarding star rating methodology through communication channels which may include special listening sessions, Open Door Forums, a TEP, and other opportunities. Additionally, we will benefit from lessons learned from the development and implementation of the star ratings in other quality reporting programs to help guide development of star ratings for hospice. Finally, we will announce the timeline for development and implementation of Hospice star ratings in future rulemaking, which will provide additional opportunity for stakeholders to provide public feedback on any proposed star rating methodology.

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. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

Unless noted otherwise, all salary information is from the Bureau of Labor Statistics (BLS) Web site at *http://www.bls.gov/oes* and includes a fringe benefits package worth 100 percent of the base salary. The mean hourly wage rates are based on May, 2015 BLS data for each discipline.

Section 1814(i)(5)(C) of the Act requires that each hospice submit data to the Secretary on quality measures specified by the Secretary. This data must be submitted in a form and manner, and at a time specified by the Secretary.

We solicited public comment and received no comments on each of these issues for the following sections of this document that contain information collection requirements (ICRs) and are finalizing them.

A. Hospice Item Set (OMB Control Number 0938–1153)

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 7 NQF endorsed measures 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).

We finalized the following two additional measures in the FY 2017 Hospice Wage Index final rule affecting FY 2019 payment determinations (81 FR 52163 through 52173):

- Hospice Visits when Death is Imminent
- Hospice and Palliative Care Composite Process Measure—Comprehensive Assessment at Admission

Data for the aforementioned 9 measures is collected via the HIS as discussed in the FY 2017 Hospice Wage Index final rule (81 FR 52189) and covered under OMB control number 0938–1153. The HIS V2.00.0 was approved by the Office of Management and Budget on April 17, 2017 under control number 0938–1153. We are not making any new updates or additional collections of information in this rule in regards to the Hospice Item Set or its constituent quality measures.

B. Summary of CAHPS® Hospice Survey Information Collection Requirements (OMB Control Number 0938–1257)

National Implementation of the Hospice Experience of Care Survey (CAHPs Hospice Survey) data measures are covered under OMB control number 0938–1257 and is summarized here for convenience. We have implemented patient experience surveys in a number of settings including Medicare, Medicare Advantage, and Part D Prescription Drug Plans, hospitals, and home health agencies. Other CAHPS® surveys exist for hemodialysis facilities, nursing homes, and physician practices. The hospice survey differs from most other CMS patient experience surveys because its target population is bereaved family members or close friends of patients who died in hospice care. Family members and friends are the best source of information regarding the entire trajectory of hospice care. In addition, many hospice patients are very ill and unable to answer survey questions.

Surveys are administered by CMS-approved survey vendors hired by hospice providers to conduct the survey on their behalf. The survey vendor may collect data in one of three modes: Mail-only, telephone-only, or mixed mode (mail with telephone follow-up). The sample consists of bereaved family members or close friends of patients who died while receiving hospice care (1) at home, (2) in a nursing home, or (3) an inpatient setting (that is, freestanding inpatient unit or acute care hospital). The questionnaire is composed of 47 items.

The estimated annualized burden hours and costs to respondents for the national implementation of the CAHPS® Hospice Survey are shown in Tables 18 and 19. Based on participation in national implementation in the CAHPS® Hospice Survey from Quarter 2 2015 through Quarter 1 2016, we assume that

3,414 hospices will administer the survey to an average of 278.7 cases. Thus, we estimate that the CAHPS® Hospice Survey will be administered to a maximum of 951,482 individuals each year for the duration of the collection period covered by this application for the purposes of national implementation. As not all sampled cases will complete the survey, this estimate reflects the maximum burden possible. The estimated number of responses is based on actual hospice participation in national implementation of the CAHPS® Hospice Survey. Table 18 shows the estimated annualized burden for the respondents' time to participate in the national implementation data collection. The survey contains 47 items and is estimated to require an average administration time of 10.4 minutes in English (at a pace of 4.5 items per minute) and 12.5 minutes in Spanish (assuming 20 percent more words in the Spanish translation), for an average response time of 10.47 minutes or 0.174 hours (assuming that 1 percent of survey respondents complete the survey in Spanish). These burden and pace estimates are based on CMS' experience with the CAHPS® Hospice Survey and surveys of similar length that were fielded with Medicare beneficiaries. As indicated below, the annual total burden hours for survey participants are estimated to be 165,959.57 for the continued national implementation of the survey.

TABLE 18—ESTIMATED ANNUALIZED BURDEN HOURS FOR RESPONDENTS: NATIONAL IMPLEMENTATION OF THE CAHPS® HOSPICE SURVEY

Survey version	Number of respondents	Number of responses per respondent	Hours per response	Total burden hours
CAHPS® Hospice Survey	951,482	1	0.174	165,959.57
Total	951,482	1	0.174	165,959.57

Table 19 shows the cost burden to respondents associated with their time to complete a survey as part of national implementation. The annual total cost burden is estimated to be $7,710,481.60. This estimate is higher than the $3,034,789.70 estimated in the prior OMB filing, due to the increased number of hospices participating (and correspondingly, the increased number of respondents), as well as an increase in the average hourly rate.

TABLE 19—ESTIMATED ANNUALIZED COST BURDEN FOR RESPONDENTS: NATIONAL IMPLEMENTATION

Form name	Number of respondents	Total burden hours	Average hourly wage rate *	Total cost burden
CAHPS® Hospice Survey	951,482	165,959.57	* $46.46	$7,710,481.60
Total	951,482	165,959.57	* 46.46	7,710,481.60

* Source: Data from the U.S. Bureau of Labor Statistics' May 2015 National Occupational Employment and Wage Estimates for all salary estimates (*http://www.bls.gov/oes*). This figure includes a 100% fringe benefit on an average wage of $23.23. Retrieved April 10, 2017.

V. Regulatory Impact Analysis

A. 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 2018 as required under section 1814(i)(1)(C)(ii)(VII) of the Act. Section 411(d) of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) amended section 1814(i)(1)(C) of the Act such that for hospice payments for FY 2018, the market basket percentage increase shall be 1 percent. 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.

B. Overall Impacts

We estimate that the aggregate impact of the payment provisions in this final rule will result in an increase of $180 million in payments to hospices, resulting from the hospice payment update percentage of 1.0 percent. The impact analysis of this final rule represents the projected effects of the changes in hospice payments from FY 2017 to FY 2018. Using the most recent data available at the time of rulemaking, in this case FY 2016 hospice claims data, we apply the current FY 2017 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 2017 payments. Then, using the same FY 2016 data, we apply the FY 2018 wage index and labor-related share values to simulate FY 2018 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.

We have examined the impacts of this rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104–4), Executive Order 13132 on Federalism (August 4,

1999), the Congressional Review Act (5 U.S.C. 804(2) and Executive Order 13771 on Reducing Regulation and Controlling Regulatory Costs (January 30, 2017).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Section 3(f) of Executive Order 12866 defines a ''significant regulatory action'' as an action that is likely to result in a rule: (1) Having an annual effect on the economy of $100 million or more in any 1 year, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or state, local or tribal governments or communities (also referred to as ''economically significant''); (2) creating a serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raising novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order.

A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any 1 year). We estimate that this rulemaking is ''economically significant'' as measured by the $100 million threshold, and hence also a major rule under the Congressional Review Act. Accordingly, we have prepared a RIA that, to the best of our ability presents the costs and benefits of the rulemaking.

C. Anticipated Effects

The Regulatory Flexibility Act (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 greater than 5 percent of providers reach a threshold of 3 to 5 percent or more of total revenue or total costs. The effect of the FY 2018 hospice payment update percentage results in an overall increase in estimated hospice payments of 1.0 percent, or $180 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.

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 2017, that threshold is approximately $148 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 $148 million or more.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on state and local governments, preempts state law, or otherwise has Federalism implications. We have reviewed this final rule under these criteria of Executive Order 13132, and have determined that it will not impose substantial direct costs on state or local governments.

If regulations impose administrative costs on private entities, such as the time needed to read and interpret this final rule, we should estimate the cost associated with regulatory review. Due to the uncertainty involved with accurately quantifying the number of entities that will review the rule, we assume that the total number of unique commenters on the published proposed rule will be the number of reviewers of this final rule. We acknowledge that this assumption may understate or overstate the costs of reviewing this final rule. It is possible that not all commenters reviewed the proposed rule in detail, and it is also possible that some reviewers chose not to comment on the proposed rule. For these reasons we thought that the number of comments received on the proposed rule would be a fair estimate of the number of reviewers of this final rule. We also recognize that different types of entities are in many cases affected by mutually exclusive sections of this final rule, and therefore for the purposes of our estimate we assume that each reviewer reads approximately 50 percent of the rule. Using the wage information from the BLS for medical and health service managers (Code 11–9111), we estimate that the cost of reviewing this rule is $105.16 per hour, including overhead and fringe benefits (*https://www.bls.gov/oes/current/oes_nat.htm*). Assuming an average reading speed, we estimate that it would take approximately 1.6 hours for the staff to review half of this rule. For each hospice that reviews the rule, the estimated cost is $168.26 (1.6 hours × $105.16). Therefore, we estimate that the total cost of reviewing this regulation is $15,143.40 ($168.26 × 90 reviewers).

A summary of the comments we received on the RIA and our responses to those comments are set forth below.

Comment: A commenter disagreed with CMS' assertion the proposed rule will not create a significant economic impact on a substantial number of small entities. The commenter believes that the impact of the overall increase will not be felt proportionally across hospices. Small hospices will face significant financial hardships, especially those with fewer data collection resources, who would be subject to the 2 percent penalty for inadequate quality data submission. The commenter encouraged CMS to provide a more detailed analysis of the impact on hospices, especially small and rural hospices.

Response: Hospices are estimated to receive a 1 percent increase in payments in FY 2018. Based on our analysis, we concluded that the policies in the proposed rule would not result in an estimated total adverse impact of 3 to 5 percent or more on Medicare revenue for greater than 5 percent of hospices. The 1 percent payment update is statutorily-mandated by MACRA (Pub. L. 114–10, enacted April 16, 2015). Furthermore, we believe that Table 20 sufficiently describes the impact on rural hospices as well as small hospices (as measured by the number of RHC days).

Comment: A commenter agreed that if regulations impose administrative costs on private entities, such as the time needed to read and interpret the proposed rule, CMS should estimate the cost associated with regulatory review. The commenter stated that CMS should not assume that the number of commenters equates to the number of reviewers. Many individual hospices, especially smaller hospices, may not submit an individual comment but instead will collaborate with their professional associations to provide comments. However, each hospice still thoroughly reviews, engages in background research, interprets and assesses the impact of proposals on current practice, as well as how practices may need to shift if proposals are finalized, in order to engage in those collective processes to prepare a comment letter.

Response: We thank the commenter for proving feedback on the methodology used to determine the costs associated with regulatory review. We will take the comment under consideration for any future refinements to the methodology used to determine the costs of regulatory review. As noted previously, we already take many of these costs into account.

D. Detailed Economic Analysis

The FY 2018 hospice payment impacts appear in Table 20. We tabulate the resulting payments according to the classifications in Table 20 (for example, facility type, geographic region, facility ownership), and compare the difference between current and future 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 2018 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 2018 hospice wage index.

The fourth column shows the effect of the hospice payment update percentage for FY 2018. The FY 2018 hospice payment update percentage of 1 percent is mandated by section 1814(i)(1)(C) of the Act, as amended by section 411(d) of the MACRA.

The fifth column shows the effect of all the changes on FY 2018 hospice payments. It is projected that aggregate payments will increase by 1.0 percent, assuming hospices do not change their service and billing practices.

As illustrated in Table 20, 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 2018 payments range from a 0.9 percent decrease for hospices providing care in the rural outlying region to a 1.7 percent increase for hospices providing care in the urban Pacific region.

TABLE 20—PROJECTED IMPACT TO HOSPICES FOR FY 2018

(1)	Number of providers (2)	Updated wage data (%) (3)	FY 2018 hospice payment update (%) (4)	FY 2018 total change (%) (5)
All Hospices	4,355	0.0	1.0	1.0
Urban Hospices	3,381	0.0	1.0	1.0
Rural Hospices	974	0.1	1.0	1.1
Urban Hospices—New England	134	−0.7	1.0	0.3
Urban Hospices—Middle Atlantic	252	0.1	1.0	1.1
Urban Hospices—South Atlantic	430	−0.3	1.0	0.7
Urban Hospices—East North Central	407	−0.1	1.0	0.9
Urban Hospices—East South Central	159	0.0	1.0	1.0
Urban Hospices—West North Central	233	−0.2	1.0	0.8
Urban Hospices—West South Central	662	0.0	1.0	1.0
Urban Hospices—Mountain	327	−0.1	1.0	0.9
Urban Hospices—Pacific	736	0.7	1.0	1.7
Urban Hospices—Outlying	41	−0.6	1.0	0.4
Rural Hospices—New England	23	0.0	1.0	1.0
Rural Hospices—Middle Atlantic	40	0.6	1.0	1.6
Rural Hospices—South Atlantic	135	0.1	1.0	1.1
Rural Hospices—East North Central	141	0.2	1.0	1.2
Rural Hospices—East South Central	124	−0.1	1.0	0.9
Rural Hospices—West North Central	181	0.2	1.0	1.2
Rural Hospices—West South Central	180	0.1	1.0	1.1
Rural Hospices—Mountain	101	0.2	1.0	1.2
Rural Hospices—Pacific	46	0.3	1.0	1.3
Rural Hospices—Outlying	3	−1.9	1.0	−0.9
0–3,499 RHC Days (Small)	1,004	0.2	1.0	1.2
3,500–19,999 RHC Days (Medium)	2,017	0.1	1.0	1.1
20,000+ RHC Days (Large)	1,334	0.0	1.0	1.0
Non-Profit Ownership	1,059	0.0	1.0	1.0
For Profit Ownership	2,735	0.1	1.0	1.1
Government Ownership	155	−0.3	1.0	0.7
Other Ownership	406	−0.2	1.0	0.8
Freestanding Facility Type	3,379	0.0	1.0	1.0
HHA/Facility-Based Facility Type	976	0.0	1.0	1.0

Source: FY 2016 hospice claims from the Chronic Condition Data Warehouse (CCW) Research Identifiable File (RIF) in June 2017.
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.

E. Accounting Statement

As required by OMB Circular A–4 (available at *http://www.whitehouse.gov/omb/circulars/a004/a-4.pdf*), in Table 21, we have prepared an accounting statement showing the classification of the expenditures associated with the provisions of this final rule. Table 21 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 4,355 hospices in our impact analysis file, which was constructed using FY 2016 claims available in June 2017. All expenditures are classified as transfers to hospices.

TABLE 21—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED TRANSFERS AND COSTS, FROM FY 2017 TO FY 2018

Category	Transfers
Annualized Monetized Transfers.	$180 million *
From Whom to Whom?.	Federal Government to Medicare Hospices.

* The net increase of $180 million in transfer payments is a result of the 1.0 percent hospice payment update compared to payments in FY 2017.

F. Reducing Regulation and Controlling Regulatory Costs

Executive Order 13771, entitled ''Reducing Regulation and Controlling Regulatory Costs,'' was issued on January 30, 2017 (82 FR 9339, February 3, 2017). It has been determined that this final rule is a transfer rule that does not impose more than de minimis costs as described above and thus is not a regulatory or deregulatory action for the purposes of Executive Order 13771.

G. Conclusion

We estimate that aggregate payments to hospices in FY 2018 will increase by $180 million, or 1.0 percent, compared to payments in FY 2017. We estimate that in FY 2018, hospices in urban and rural areas will experience, on average, 1.0 percent and 1.1 percent increases, respectively, in estimated payments compared to FY 2017. Hospices providing services in the urban Pacific and rural Middle Atlantic regions will experience the largest estimated increases in payments of 1.7 percent and 1.6 percent, respectively. Hospices serving patients in urban areas in the New England region will experience, on average, the lowest estimated increase of 0.3 percent in FY 2018 payments.

In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

Dated: July 25, 2017.

Seema Verma,

Administrator, Centers for Medicare & Medicaid Services.

Dated: July 27, 2017

Thomas E. Price,

Secretary, Department of Health and Human Services.

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